UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SHAWN SHANAWAZ, Individually and On Behalf of All Others Similarly Situated, Plaintiff, vs. INTELLIPHARMACEUTICS INTERNATIONAL INC., ISA ODIDI and DOMENIC DELLA PENNA, Defendants.	**Case No. 1:17-cv-05761-JPO** **AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

1. Lead Plaintiffs David Ducharme, Sam Snyder, and Julia Ann Synder and additional Plaintiffs Guy Braverman and Eric Ludwig (collectively, "Plaintiffs") bring this federal securities class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure, on behalf of the purchasers of Intellipharmaceutics International Inc. ("IPCI" or the "Company") securities between May 21, 2015 and July 26, 2017 (the "Class Period"), against IPCI, its Chief Executive Officer ("CEO") and Chief Scientific Officer ("CSO") Isa Odidi ("Odidi") and its former Chief Financial Officer ("CFO"), Domenic Della Penna ("Della Penna")[1] (collectively, "Defendants") for violations of the Securities Exchange Act of 1934 (the "Exchange Act").

2. Plaintiffs allege the following based upon the investigation of Plaintiffs' counsel, which included a review of United States Securities and Exchange Commission ("SEC") filings by IPCI, securities analysts' reports and advisories about the Company, press releases, other public statements issued by the Company and its executives, media reports about IPCI, and

[1] Collectively, Odidi and Della Penna are referred to herein as the "Individual Defendants."

interviews with witnesses with knowledge of the allegations herein. Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

OVERVIEW

3. This federal securities fraud action concerns a pharmaceutical company, IPCI, which misled investors regarding the New Drug Application ("NDA") for the Company's main product candidate, Rexista, an abuse-deterrent oxycodone hydrochloride extended release tablet. During the Class Period, IPCI and the Individual Defendants repeatedly told investors that the Company was developing a promising, "best in class" abuse-deterrent opioid tablet with numerous advantages over existing abuse-deterrent opioid tablets. Rexista provided Defendants with an opportunity to, *inter alia*, generate revenues, attract outside investment, infuse much-needed capital into the Company, and obtain lucrative compensation and performance-based options tied to filings with the U.S. Food and Drug Administration ("FDA").

4. In order to receive approval from the FDA, drugs must first demonstrate safety and efficacy through a series of clinical trials. In an effort to combat the opioid crisis, in April 2015, the FDA issued a guidance document, "Abuse-Deterrent Opioids – Evaluation and Labeling," to assist the pharmaceutical industry in developing new formulations of opioid drugs with abuse-deterrent properties. Generally, the 2015 FDA Guidance recommends that sponsors evaluate known routes of abuse for a drug (*e.g.*, oral, intranasal, and intravenous ("IV")), and any development program for studying abuse-deterrent technologies should include three categories of premarket studies (Category 1, 2, and 3).

5. Throughout the Class Period, Defendants made numerous materially false and/or misleading statements and omissions regarding the promise of Rexista, Rexista's NDA,

Rexista's abuse-deterrent properties, and the clinical studies and trials by which IPCI purportedly established Rexista's abuse-deterrent properties. For example, Defendants repeatedly assured investors that "[t]he [NDA] ***submission also includes a comprehensive array of abuse-deterrent studies*** conducted to support abuse-deterrent label claims ***related to abuse of drug by oral***, ***intra-nasal and intravenous pathways***, ***having reference to the FDA's 'Abuse-Deterrent Opioids – Evaluation and Labelling" guidance published in April 2015***.'" *See*, *e.g.*, Form 6-K Press Release dated November 25, 2016 (emphasis added).

6. For at least two months prior to a critical FDA advisory committee meeting where the approval of Rexista would effectively be decided, and unable to secure a partner for Rexista who would infuse needed funds into IPCI, Defendant Odidi pursued other opportunities with a private pharmaceutical company he founded and incorporated in China.[2] The new Chinese company, Smart Pharmaceutical (Shanghai) Co., Ltd., is described as an innovative pharmaceutical company that will set up the largest R&D center for controlled-release drugs in Shanghai.[3] The description of Smart Pharmaceutical is noticeably similar to the description provided for IPCI on its own website: "At Intellipharmaceutics, we are engaged in the research, development and commercialization of controlled-release and targeted pharmaceutical products…."

7. Despite the obvious materiality of this information, neither IPCI nor Defendant Odidi disclosed that IPCI's founder and current CEO started a new, private Chinese company in the same industry as IPCI. Instead, on January 24, 2018, IPCI issued a materially misleading press release denying that the Company had entered into any arrangement in China: "[Although]

[2] Indeed, a YouTube video recently published by a Nigerian newspaper, the Daily Trust, notes that Defendant Odidi and his wife "had established a similar company [to Smart Pharmaceutical] in Canada called Intellipharmaceutics International." *See* https://www.youtube.com/watch?v=fwNtMklYbKY

[3] http://www.yunfeng-medicine.com/index.php/2017/12/16/cooperate/

[t]he Company recently visited China where discussions toward establishing a partnership to facilitate future development activities are ongoing[,] [t]he Company has not entered into any such arrangements at this time." *See* Ex. 99.1 to January 24, 2018 Form 6-K. The press release, however, omits whether Defendant Odidi entered into any arrangements in China or whether he has a stake in Smart Pharmaceutical (Shanghai) Co., Ltd. or any other Chinese pharmaceutical companies. These undisclosed material facts call into question Defendant Odidi's commitment to the success of IPCI and Rexista, and raise red flags regarding potential conflicts of interest and duties owed to IPCI's shareholders.

8. Defendants were also motivated to issue false and misleading statements (and others) regarding the Company's potential for obtaining FDA approval of Rexista for financial reasons. Throughout the Class Period, the Company was critically low on cash and had posted only net losses totaling approximately $23 million. In order to stem the flow of losses and boost cash on hand, the Company was purportedly attempting to secure a partner for Rexista to infuse much needed funds into the Company. Another avenue that IPCI had to regularly rely on to raise funds was selling the Company's common shares under its at-the-market offering ("ATM") program. Because shares in an ATM are sold at prevailing market prices, Defendants were also motivated to issue false and misleading statements regarding the Company's potential for obtaining FDA approval of Rexista in order to keep IPCI's stock at artificially inflated levels throughout the Class Period. Therefore, Defendants were motivated to issue materially false and misleading statements in order to improve their chances of securing a lucrative partnership for Rexista and so IPCI could raise cash at inflated levels to infuse much needed funds into the Company.

9. Defendants' false and misleading statements caused the price of IPCI's common stock to rise from $2.71 on May 20, 2015, the day before IPCI announced that it intended to accelerate the development of Rexista, to a Class Period-high of $3.92 on May 26, 2015, just five days after the start of the Class Period.

10. Unbeknownst to investors, however, Defendants did not follow the 2015 FDA Guidance because it submitted only Category 1 (in vitro) studies to support labeling for abuse-deterrent properties *only* for the intravenous route of abuse and not also for the nasal and oral routes of abuse. Indeed, the FDA Advisory Committee noted from the start that "[t]he results of [IPCI's] in vitro physical and chemical manipulation studies will be presented during this meeting. However, ***no clinical studies*** of the pharmacokinetic effects of manipulation or pharmacodynamic endpoints ***were conducted as recommended in the guidance***." Tr. 30:22-31:5[4] (emphasis added). Furthermore, an FDA report noted: "The safety information collected in the pharmacokinetic studies was of limited value … [and] [t]here were no human abuse liability studies submitted with the NDA."

11. As a result, an FDA advisory committee overwhelmingly rejected recommending approval of Rexista. Numerous committee members slammed IPCI for the lack of quality and completeness of the information submitted with its Rexista NDA. One committee member summarized the committee's feelings regarding the Rexista NDA submission: "Let me try to summarize a bit and say that these guidelines were begun to be worked on in 2012, and they're very well written. They had been commented on by hundreds of clinicians and scientists across the country. They're very clear. The panel believes, and I believe, that ***the guidelines need to be***

[4] "Tr." citations refer to the July 26, 2017 Transcript from the Open Session of the FDA's Joint Meeting of the Anesthetic and Analgesic Products and Drug Safety and Risk Management Advisory Committees' Meeting.

followed. ***I think the committee feels uncomfortable in providing a signal that it's all right to present incomplete data and expect a positive outcome.***" Tr. 261:15-262:3 (emphasis added).

12. The truth regarding Rexista and the Rexista NDA began to be revealed to the market on July 24, 2017, when the FDA released a scathing report in advance of the FDA advisory committee meeting, and was fully revealed to the market on July 26, 2017, when the Company announced that an FDA advisory committee voted 22 to 1 in finding that the Company's NDA for Rexista should not be approved; voted 19 to 4 that IPCI had not demonstrated that Rexista has properties that can be expected to deter abuse by the IV route of administration; and voted 23 to 0 that IPCI did not provide sufficient data to support inclusion of language regarding abuse deterrent properties in the Rexista product label for the IV route of administration.

13. As a result of the revelations of the true facts, the price of shares of IPCI's common stock fell, on heavy trading volume, from an opening price of $2.80 on July 24, 2017, to close at $2.42 at the end of trading on that same day. This drop represented a decline of approximately 14%. Upon the July 26, 2017 announcement, IPCI shares plummeted from $2.49 per share at close on July 26, 2017, to close at $1.36 per share on July 27, 2017—a massive decline of over 45%. As a consequence of Defendants' materially false and misleading statements and omissions that obscured true facts revealed on July 24 and 26, 2017, which resulted in precipitous declines in IPCI's stock value, Plaintiffs and the Class suffered significant losses and damages.

JURISDICTION AND VENUE

14. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act [15 U.S.C. §§ 78j(b) and 78t(a)] and Rule 10b-5 promulgated thereunder by

the SEC [17 C.F.R. § 240.10b-5].

15. This Court has jurisdiction over the subject matter of this action pursuant to §28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act [15 U.S.C. § 78aa].

16. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b), as the Company's common stock trades on the NASDAQ, located within this District.

17. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

A. Plaintiffs

18. Lead Plaintiff DAVID DUCHARME, as set forth in his previously-filed certifications (*see* D.E. 1-1 from 1:17-cv-6621 and D.E. 17-1), incorporated herein by reference, purchased IPCI securities at artificially inflated prices during the Class Period, and was harmed when the true facts were revealed and the artificial inflation was removed from the price of the stock at the end of the Class Period.

19. Lead Plaintiff SAM SNYDER, as set forth in his previously-filed certification (*see* D.E. 17-1), incorporated herein by reference, purchased IPCI securities at artificially inflated prices during the Class Period, and was harmed when the true facts were revealed and the artificial inflation was removed from the price of the stock at the end of the Class Period.

20. Lead Plaintiff JULIA ANN SNYDER, as set forth in her previously-filed certification (*see* D.E. 17-1), incorporated herein by reference, purchased IPCI securities at

artificially inflated prices during the Class Period, and was harmed when the true facts were revealed and the artificial inflation was removed from the price of the stock at the end of the Class Period.

21. Additional Plaintiff GUY BRAVERMAN, as set forth in his previously-filed certifications (*see* D.E. 1 from 1:17-cv-6045 and D.E. 20-2), incorporated herein by reference, purchased IPCI securities at artificially inflated prices during the Class Period, and was harmed when the true facts were revealed and the artificial inflation was removed from the price of the stock at the end of the Class Period.

22. Additional Plaintiff ERIC LUDWIG, as set forth in his previously-filed certification (*see* D.E. 20-2), incorporated herein by reference, purchased IPCI securities at artificially inflated prices during the Class Period, and was harmed when the true facts were revealed and the artificial inflation was removed from the price of the stock at the end of the Class Period.

B. Company Defendant

23. Defendant INTELLIPHARMACEUTICS INTERNATIONAL INC. is incorporated in Canada, with principal executive offices located at 30 Worcester Road, Toronto, ON M9Q 5X2, Canada. As explained above, IPCI is a pharmaceutical company specializing in the research, development, and manufacture of novel and generic controlled-release and targeted-release oral solid dosage drugs. Throughout the Class Period, the Company's securities traded on the NASDAQ exchange under the ticker symbol "IPCI."

C. Individual Defendants

24. Defendant ISA ODIDI served at all relevant times as the Company's CEO and CSO. Defendant Odidi made materially false and misleading statements and omissions during

the Class Period, and personally certified all of the Company's financial reports issued during the Class Period. In the course of Plaintiffs' investigation, Plaintiffs discovered that in May 2017, Defendant Odidi founded Smart Pharmaceutical (Shanghai) Co., Ltd. IPCI has not disclosed this information.

25. Defendant DOMENIC DELLA PENNA served at all relevant times as the Company's CFO. Defendant Della Penna made material false and misleading statements and omissions during the Class Period, and personally certified all of the Company's financial reports issued during the Class Period.[5]

FACTUAL BACKGROUND AND SUBSTANTIVE ALLEGATIONS

A. IPCI Business Overview

26. Founded in 1998 as Intellipharmaceutics Ltd., IPCI reorganized and took its current name in 2009. Currently, IPCI is a pharmaceutical company purportedly engaged in the research, development, and commercialization of controlled-release and targeted pharmaceutical products, both novel and generic, with a particular emphasis in the opioid abuse deterrence space.

27. A primary focus of IPCI's business is a drug in development called Rexista. Rexista is purportedly an investigational abuse-deterrent extended-release (ER) oxycodone hydrochloride (HCl) product intended for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. It was ostensibly formulated with a combination of chemical barriers and aversion techniques intended to deter abuse in the treatment of pain requiring around-the-clock opioid treatment. The features intended to deter abuse purportedly include:

- Formulated to gel more quickly with greater particle size reduction;

[5] Defendant Della Penna resigned from IPCI effective September 1, 2017, after the Class Period ended.

- Resistance to chemical extraction in small volumes of solvents intended to make abuse via injection difficult;
- Gelling upon contact with aqueous solutions to deter intravenous (IV) abuse;
- Resistance to chemical extraction in large volumes of solvents;
- Resistance to dose dumping in the presence of alcohol;
- Nasal irritant; and
- Staining blue dye that releases if crushed or chewed, which is hard to remove from the face, hands, and tongue.

28. While IPCI's product portfolio contains other drugs, Rexista was a primary focus of IPCI's business because the market opportunity for abuse-deterrent opioid tablets provided IPCI with the perfect platform for attracting outside investment and generating revenue. Indeed, according to the Centers for Disease Control and Prevention, the U.S. opioid epidemic is ongoing, and drug overdose deaths nearly tripled between 1999 and 2014. Of the 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid. Moreover, between 2015 and 2016, 24.6 million Americans lived with substance dependence or abuse; 1.9 million Americans lived with prescription opioid abuse or dependence; there were 33,091 deaths in 2015 from prescription opioids, which represented a 14% increased rate of opioid overdose deaths from 2014 to 2015; and opioid abuse accounts for $50 billion in direct healthcare costs.

29. Recognizing an opportunity to profit from the U.S. opioid epidemic, IPCI embarked on a journey to obtain approval from the FDA for Rexista.

B. Overview of the FDA Review and Approval Process

30. After a drug is developed and initial testing is completed, a sponsor submits an Investigation New Drug Application ("IND") to the FDA based on results from the initial testing that include the drug's composition and manufacturing and develops a plan for testing the drug on humans. The FDA then reviews the IND to ensure that proposed studies, generally referred to as clinical trials, do not place human subjects at unreasonable risk of harm.

31. Next, FDA regulations typically require that drug manufacturers engage in three phases of clinical trials (Phase I, II, and III) before presenting a new drug to the FDA for approval. Once a pharmaceutical company has completed all three phases of clinical trials, unless an exception applies, it can submit an NDA to the FDA. Once the FDA has accepted an NDA, it may refuse to approve it for a variety of substantive reasons. As part of the process, the FDA can use "advisory committees" to provide independent advice that will contribute to the quality of the FDA's regulatory decision-making and lend credibility to the product review process. Advisory committees, in addition to guiding overall recommendation for or against approval, are also instrumental in guiding label claims. If the FDA determines that it will not approve an NDA in its present form, it will send the applicant a Complete Response Letter ("CRL") that describes the deficiencies in the application and, where possible, provides recommendations for achieving approval.

C. 2015 FDA Guidance Regarding Abuse-Deterrent Opioids

32. As a result of the opioid crisis, in April 2015, the FDA issued final guidance entitled, "Abuse-Deterrent Opioids – Evaluation and Labeling," to assist the pharmaceutical industry in developing new formulations of opioid drugs with abuse-deterrent properties.[6] "FDA guidance" is the "FDA's current thinking about studies that ***should*** be conducted to demonstrate that a given formulation has abuse-deterrent properties. The guidance makes recommendations about how those studies should be performed and evaluated and discusses how to describe those studies and their implications in product labeling." (Emphasis added). While FDA guidance is not required, the guidance is explicitly suggested and recommended.

33. Initially, the 2015 FDA Guidance states that:

[6] The 2015 FDA Guidance can be found on the FDA website: https://www.fda.gov/downloads/Drugs/Guidances/UCM334743.pdf

> ***[A]ny studies designed to evaluate the abuse-deterrent characteristics of an opioid formulation should be scientifically rigorous***. ***The evaluation of an abuse-deterrent formulation should take into consideration the known routes of abuse for the non-abuse-deterrent predecessor or similar products, as well as anticipate the effect that deterring abuse by one route may have on shifting abuse to other, possibly riskier route***. For example, if a product is known to be abused using nasal and intravenous routes, developing deterrent properties for the nasal route in the absence of deterrent properties for the intravenous route risks shifting abusers from the nasal to the intravenous route, which is associated with a greater risk for the spread of infectious diseases.
>
> Another concept that should be considered is whether the deterrent effects can be expected to have a meaningful impact on the overall abuse of the product.

(Emphasis added).

34. The 2015 FDA Guidance further provides: "[I]n general, any development program for studying abuse-deterrent technologies ***should include data from all three categories of [premarket] studies***." (Emphasis added). "In most cases, ***to obtain a full and scientifically rigorous understanding of the impact of a technology or technologies on a product's abuse potential***, data from ***each*** of the following three categories of premarket studies are appropriate: (i) Laboratory-based in vitro manipulation and extraction studies (Category 1); (ii) Pharmacokinetic studies (Category 2); and (iii) Clinical abuse potential studies (Category 3)." *Id*. (Emphasis added). These studies focus on assessing the potentially abuse-deterrent properties of a product under controlled conditions.

35. The goal of laboratory-based Category 1 studies should be to evaluate the ease with which the potentially abuse-deterrent properties of a formulation can be defeated or compromised. *See* 2015 FDA Guidance. The goal of Category 2 should be to understand the in vivo properties of the formulation by comparing the pharmacokinetic[7] profiles of the manipulated formulation with the intact formulation and with manipulated and intact

[7] Pharmacokinetics is a branch of pharmacology dedicated to determining the fate of substances administered to a living organism.

formulations of the comparator drugs through one or more routes of administration. *See id*. Category 3 studies are important for assessing the impact of potentially abuse-deterrent properties. *See id.*

36. All three premarket studies are important because "[t]he results of Category 1 studies may influence the design of Category 2 pharmacokinetic studies and Category 3 clinical abuse potential studies by suggesting the methods of manipulation that would yield the greatest release of opioid [and] [t]he results of Category 2 studies may influence the need for Category 3 studies of clinical abuse potential and the designs and goals of these studies." *Id*.

37. The FDA also "encourages sponsors to propose labeling that sets forth the results of in vitro, pharmacokinetic, clinical abuse potential, and formal postmarket studies and appropriately characterizes the abuse-deterrent properties of a product." *Id*.

D. Rexista IND and NDA

38. According to the FDA, an IND is the vehicle through which a sponsor advances to the next stage of drug development known as clinical trials (human trials). Confidential Witness ("CW") 1, who worked at IPCI as the Manager, Regulatory Affairs from February 2008 to June 2015, and reported to Dr. Amina Odidi the President, Chief Operating Officer, and Co-Chief Scientific Officer, stated that prior to submitting an NDA, pharmaceutical companies meet with the FDA to have a dialogue regarding what studies and information will be submitted with and sufficient for the NDA. CW 1 stated that a similar IND meeting occurred between IPCI and the FDA regarding Rexista.

39. With respect to the Rexista NDA, several CWs stated that Defendant Odidi was a key person in any NDA submission, and he would have been central to the review and approval of any information included in every NDA. Specifically, CW 2, who was an analytical chemist at

IPCI from February 2014 to May 2016, stated that all NDA submissions would have to go through Defendant Odidi, who had a Ph.D. in Pharmaceutics, and Defendant Odidi was a key person in any NDA submission. According to CW 2, Defendant Odidi was central to the review and approval of any information included in every NDA. CW 3 was an executive assistant at IPCI from November 2009 to November 2016 and reported directly to Defendant Odidi and the other members of the executive team. During his/her employment, CW 3 routinely interacted with Defendant Odidi, Defendant Della Penna, and, to a lesser extent, Dr. Amina Odidi. Notably, CW 3 stated that the NDA process for Rexista was the responsibility of Defendant Odidi and the Company's other top executives. CW 4 was a Regulatory Affairs Associate at the Company from May 2016 to October 2017, and also worked as a Regulatory Affairs Intern at IPCI between May 2015 and May 2016, reporting directly to Dr. Amina Odidi. CW 4 stated that IPCI's senior leadership was "tight," that they controlled the NDA process, and that Defendant Odidi was a key person in all NDAs. Therefore, Defendant Odidi and other IPCI executives would have been intimately familiar with all aspects of the Rexista NDA.

40. On March 30, 2015, before the start of the Class Period, the Company announced its submission of an IND to the FDA for Rexista "in anticipation of the commencement of Phase III clinical trials." *See* Ex. 99.1 to March 30, 2015 Form 6-K. IPCI also announced at this time that it had recently conducted and analyzed Phase I pharmacokinetic clinical trials for Rexista, and that those trials all met bioequivalence[8] criteria when compared to the existed branded drug OxyContin. *See id*. The completion of these studies purportedly formed a basis for the Company

[8] Bioequivalence is a term in pharmacokinetics used to assess the expected in vivo biological equivalence of two proprietary preparations of a drug. If two products are said to be bioequivalent it means that they would be expected to be, for all intents and purposes, the same. Demonstrating bioequivalence could allow a company to avoid unnecessary duplication of studies already performed on a previously approved ("listed") drug. In essence, the company could potentially use the information from studies not conducted by or for the applicant to satisfy the requirements for NDA approval.

"to move forward, subject to FDA guidance and availability of funding, to Phase III trials." *See* Ex. 99.1 to April 14, 2015 Form 6-K.

41. Thereafter, on May 21, 2015—the start of the Class Period—IPCI announced, in part, that it received a notification from the FDA regarding its Rexista IND, stating "that the Company will not be required to conduct Phase III studies ***if*** bioequivalence to Oxycontin™ is demonstrated [and that] [t]he Company believes, in light of these prior results, that it will not be required to conduct Phase III studies, although no assurance to that effect can be given." *See* Ex. 99.1 to May 21, 2015 Form 6-K (emphasis added). Defendant Odidi stated, "We are thrilled with the FDA's positive acknowledgement, which enables us to accelerate the development and commercialization of our abuse deterrent Rexista™ Oxycodone XR product candidate. The avoidance of a Phase III trial eliminates a significant financial hurdle. More importantly, it shortens the development timeline and potential time to market." *Id*.

42. In response to IPCI's announcement on May 21, 2015, one analyst provided: "***We spoke with management and in fact, bioequivalence has already been demonstrated***, so their confidence that they can meet all the filing requirements is quite high." *See* May 26, 2015 Maxim Group report (emphasis added).

43. On January 14, 2016, the Company stated that "pivotal bioequivalence trials of the Company's Rexista™ Oxycodone XR (abuse deterrent oxycodone hydrochloride) extended release tablets, dosed under fasted and fed conditions, had demonstrated bioequivalence to Oxycontin," and that it now intended to file an NDA with the FDA for Rexista within the next six months. *See* Ex. 99.1 to January 14, 2016 Form 6-K.

44. On November 25, 2016, IPCI announced that it filed an NDA for Rexista, using OxyContin as a bioequivalent. IPCI repeatedly assured investors that "[t]he [NDA] submission is

supported by pivotal pharmacokinetic studies that demonstrated that Rexista® is bioequivalent to OxyContin ® (oxycodone hydrochloride extended release). ***The submission also includes a comprehensive array of abuse-deterrent studies*** conducted to support abuse-deterrent label claims related to abuse of drug by ***oral***, ***intra-nasal and intravenous pathways***, ***having reference to the FDA's "Abuse-Deterrent Opioids – Evaluation and Labelling" guidance published in April 2015***." *See, e.g.*, Form 6-K Press Release dated November 25, 2016. (Emphasis added). Therefore, at all relevant times, the Company represented that Rexista was bioequivalent to OxyContin, that IPCI was following the 2015 FDA Guidance, and that IPCI was seeking approval for labeling Rexista as an abuse-deterrent for the oral, intra-nasal, and IV routes of abuse.

45. Indeed, one analyst summarized IPCI's announcement of the Rexista NDA submission as including the following data: "The submission includes data from prior studies: 1) ***Bioequivalence to Oxycontin was successfully demonstrated*** in earlier pharmacokinetic studies; 2) ***A broad display of abuse deterrent attributes, in-line with FDA guidelines***, ***was submitted*** with the goal of gaining abuse deterrent labeling." *See* November 28, 2016 Aegis Capital Corp. Company Update (emphasis added).

46. Thereafter, on February 2, 2017, the Company announced that the FDA had accepted the Rexista NDA as being sufficient to allow substantive review and set the Prescription Drug User Fee Act ("PDUFA") target action date for September 25, 2017. The FDA subsequently scheduled a joint advisory committee meeting regarding Rexista for July 26, 2017.

47. In May 2017, an analyst at Dawson James Securities held a "fireside chat" with "Intellipharmaceutics management" to "get an update on various Company developments," including the status of the Rexista filing. *See* May 5, 2017 Dawson James Securities Company

Update. During the fireside chat, the IPCI's management reiterated that it was the Company's "goal to receive ***all three allowable deterrent claims for Rexista, which would be a significant market differentiator.***" *Id*. (emphasis added). Moreover, Company management noted that it was "focusing the majority of its resources towards the expected FDA Advisory Panel Committee review[]" to the point that it had to put some of its pipeline drugs on hold pending additional financing. *Id*.

48. Despite IPCI's statements to the contrary regarding its Rexista NDA submission to the FDA, the Company, in truth, did not follow the 2015 FDA Guidance because it submitted only Category 1 (in vitro) studies to support labeling of Rexista for abuse deterrence related to only the IV route of abuse, when IPCI should have conducted a complete abuse-deterrent assessment to cover multiple routes of administration such as oral, intranasal, and IV abuse, and should have conducted Category 2 and 3 studies because they provide important information for the evaluation of abuse deterrent formulations with respect to oral and intranasal abuse that cannot be derived from Category 1 studies alone.

49. CW 5, who reported to Dr. Amina Odidi as a contract Quality Compliance Manager at IPCI from April 2014 to April 2015, and then again from about July 2015 to October 2015, noted that the Company routinely took short cuts "[i]f there were short cuts to be taken." S/he also noted that the Company "made it sound how they wanted to make sure everything was being done [in] the proper manner [but] [t]hat didn't always necessarily come through on the action side of it." CW 5 also noted that some employees in management positions seemed to lack experience, and that the Odidis had even hired their former nanny as the head of shipping and receiving inventory. "Just overall, they had people in position that didn't have the experience to really be able to do the function," s/he said. CW 6, who was a Quality Assurance Specialist and

Manage at IPCI from August 2013 to June 2015, also confirmed that the Company did not employ the most qualified people, and the staff were not as professional or proficient as they should have been.

50. On or about July 24, 2017,[9] when the FDA made available IPCI's "FDA Advisory Committee Briefing Document,"[10] the briefing document revealed for the *first* time that IPCI submitted *only* Category 1 (in vitro) studies to support labeling for abuse-deterrent properties *only* for the IV route of abuse and not also for nasal and oral routes of abuse, which was contrary to the recommendations in the 2015 FDA Guidance:

> The current abuse-deterrent program for IPC Oxy includes a comprehensive set of ***Category 1 (in vitro) abuse-deterrence studies***, including evaluations of particle size reduction, chemical extraction, syringeability/injectability, the ability to isolate or remove the dye from IPC Oxy, alcohol dose dumping and simulated smoking/vaporization. ***These studies support the proposed IV abuse-deterrent claim for the IPC Oxy label in accordance with the FDA Guidance "Abuse-Deterrent Opioids – Evaluation and Labeling: Guidance for Industry***" (FDA, 2015).
>
> ***At this time, IPC is requesting abuse-deterrent labeling only for the IV route of abuse***. ***The primary potential abuse-deterrent features of IPC Oxy for the oral and intranasal routes (i.e., nasal irritant and blue dye) have not been formally evaluated in clinical human abuse potential (HAP) studies, which are required for abuse-deterrent labeling incorporating Category 2 (pharmacokinetic [PK]) or Category 3 (pharmacodynamic [PD]) claims for the oral and intranasal routes***.

(Emphasis added).

51. As a result, the FDA Advisory Committee noted from the start that "[t]he results of [IPCI's] in vitro physical and chemical manipulation studies will be presented during this meeting. However, ***no clinical studies*** of the pharmacokinetic effects of manipulation or pharmacodynamic endpoints ***were conducted as recommended in the guidance***." Tr. 30:22-31:5

[9] The FDA generally makes "background material available to the public no later than 2 business days before a meeting.

[10] https://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/drugs/anestheticandanalgesicdrugproductsadvisorycommittee/ucm568079.pdf

(emphasis added). While IPCI was not seeking a nasal or oral abuse-deterrent labeling at this time, it was noted that Rexista contains excipients (a nasal irritant and blue dye) that are intended to deter abuse by the nasal and oral routes, but no data was provided to support these claims.

52. In keeping with the recommendations of the 2015 FDA Guidance, IPCI should have conducted a complete abuse-deterrent assessment to cover multiple routes of administration such as oral, intranasal, and IV abuse, and should have conducted Category 2 and 3 studies because they provide important information for the evaluation of abuse deterrent formulations with respect to oral and intranasal abuse that cannot be derived from Category 1 studies alone.

53. Without relevant data in accordance with the 2015 FDA Guidance, one committee member remarked that "***[w]e don't know that there's bioequivalence for effect [compared to OxyContin]***. And I could envision a situation where whatever, the blue dye or whatever it is, mixing with the oxycodone, when you take it, it's not going to give you the same amount of analgesic activity." Tr. 252:4-253:14 (emphasis added). Put simply, without conducting the full suite of studies called for in the 2015 FDA Guidance, it is difficult to determine whether Rexista and OxyContin are, for all intents and purposes, the same.

54. Additionally, IPCI did not previously inform investors that it would be submitting "only Category 1 (in vitro) studies to support labeling of Oxycodone Extended Release tablets for abuse deterrence, and [would be] seeking labeling for abuse-deterrent properties only for the IV route of abuse[,]" and would not be requesting abuse-deterrent labeling for nasal and oral routes of abuse. To the contrary, IPCI had repeatedly told investors that its NDA submission "includes a comprehensive array of abuse-deterrent studies conducted ***to support abuse-deterrent label claims related to*** abuse of drug by ***oral, intra-nasal and intravenous pathways***, ***having reference to the FDA's "Abuse-Deterrent Opioids – Evaluation and Labelling"***

guidance published in April 2015." *See, e.g.*, Form 6-K Press Release dated November 25, 2016 (emphasis added). Thus, investors were led to believe that IPCI's Rexista NDA was in full compliance with the 2015 FDA Guidance, and thus, Rexista had a real chance to be recommended for approval.

E. The FDA Advisory Committee Meeting

55. On July 26, 2017, a Joint Meeting of the Anesthetic and Analgesic Drug Products and Drug Safety and Risk Management Advisory Committees was conducted. The FDA Advisory Committee reviewed IPCI's Rexista NDA submission to determine whether Rexista should be approved for its proposed indication for use and whether, if approved, it should be granted a label reflecting abuse-deterrent properties via the IV route.

56. Specifically, three questions were posed to the committee for a vote at the conclusion of the meeting: (1) Has IPCI demonstrated that Rexista has properties that can be expected to deter abuse by the IV route of administration? The Committee voted 19 to 4 that IPCI had not. (2) Are there sufficient data for this product to support inclusion of language regarding abuse deterrent properties in the product label for the IV route of administration? The Committee voted 23 to 0 that there were not. And (3) should this drug product be approved? The Committee voted 22 to 1 that Rexista should not be approved.

57. Predictably, but contrary to the representations made by Defendants throughout the Class Period, the FDA Advisory Committee overwhelmingly found that the IPCI's NDA should not be approved because IPCI did not follow the 2015 FDA Guidance, and thus, IPCI had submitted woefully incomplete data: "Let me try to summarize a bit and say that these guidelines were begun to be worked on in 2012, and they're very well written. They had been commented on by hundreds of clinicians and scientists across the country. They're very clear. ***The panel***

believes, and I believe, that the guidelines need to be followed. I think the committee feels uncomfortable in providing a signal that it's all right to present incomplete data and expect a positive outcome." Tr. 261:15-262:3 (emphasis added).

58. Presumably confounded by IPCI's failure to follow clear FDA guidance, one committee member asked whether the FDA perhaps gave any indications to IPCI that approval of Rexista could be obtained without complying with the 2015 FDA Guidance:

> Dr. Galinkin: [D]id the FDA give indications that just having one route, a category 1 approval, was all that was needed for approval, or did you want category 1, 2, and 3?
>
> DR. HERTZ: ***No, we provide advice that's consistent with the guidance***.
>
> ***
>
> DR. GERHARD: So to me, ***this is a pretty straightforward answer. I think, for good reason, the guidelines ask for both data that's not limited to category 1 studies and for data that looks at all routes of abuse simultaneously*** because we've seen in past meetings, certainly, that these aren't independent. Sometimes, changes in one route of abuse can affect how the drug is used in other routes of abuse. And sometimes while oftentimes the category 1 studies line up with the results for category 2 and 3 studies, there certainly can be a difference. And I believe we have seen that in the past, so they don't necessarily extrapolate from in vitro into the human experience. ***Therefore, I believe these data are, for good reason, required, and therefore, the product shouldn't be considered without the full breadth of the data being available***.

Tr. 249:13-250:17 (emphasis added).

59. Another committee member noted it would be a departure from all other drugs that have been approved with abuse-deterrent formulation ("ADF") labeling to approve Rexista because of the incomplete nature of the information submitted by IPCI:

> DR. LITMAN: So I think ***this would be a departure from all the other drugs that have been approved with ADF labeling*** for a couple reasons. Number one, I think that, up to this point, ADF labeling meant that it was deterrent in both routes…. The second thought I had is when I think about whether or not it's appropriate to consider this without -- I'm reading this, obviously -- a complete assessment -- I'm not worried about category 3 data. Category 3 data, to me, is very artificial,

> and those results really just don't come out until whatever postmarketing you can get. But category 2 to me is pretty important. ***We don't know that there's bioequivalence for effect. And I could envision a situation where whatever, the blue dye or whatever it is, mixing with the oxycodone, when you take it, it's not going to give you the same amount of analgesic activity***.

Tr. 252:4-253:14 (emphasis added).

60. The committee members also found that it would be inappropriate to predict intranasal and oral abuse deterrent effects from only Category 1 studies: "I'm going to summarize by saying that the sense of the group is that it's not acceptable to predict intranasal or oral abuse deterrent effects from category 1 studies alone for this product and that ***the best way to evaluate for the deterrent effects is to actually use the guidances provided by the FDA, which is crystal clear on this***." Tr. 290:7-14.

61. Another member commented: "[W]ithout complete assessment of all routes [of abuse] and all their potential unintended consequences, I find it to be a very concerning approach to allowing something to take on the name of being abuse deterrent." Tr. 257:13-21.

62. And regarding the blue dye contained in Rexista, one committee member stated: "To elaborate further on what was just said, I'm very concerned, apart from the guidance and where this presentation and the product falls and how it aligns with the guidance, ***that it contains this blue dye that's of no therapeutic benefit to the intended patients, we've seen no evidence of proven deterrent effect, and it doesn't support anything that's being asked to be put on the product label***. There's also no real study of harm or the risk of harm to either people who ingested because they were prescribed it for pain or who misuse it." Tr. 265:9-20 (emphasis added).

63. Finally, one committee member went as far as to suggest that the drug may not be safe when used as prescribed: "***I'm not convinced that this product is safe when used as***

prescribed…. ***This drug is not a breakthrough drug***, and I can't support this. I'm uncomfortable." Tr. 269:1-270:10 (emphasis added).

F. Post-Class Period Events

64. On September 25, 2017, IPCI announced it had received a Complete Response Letter ("CRL") from the FDA for its Rexista NDA, confirming that the FDA would not be approving the NDA in its present form. In line with the FDA Advisory Committee's findings, "the FDA provided certain recommendations and requests for information, including that Intellipharmaceutics ***complete the relevant Category 2 and Category 3 studies to assess the abuse-deterrent properties of Oxycodone ER by the oral and nasal routes of administration***. The FDA also requested additional information related to the inclusion of the blue dye in the Oxycodone ER formulation, which is intended to deter abuse." *See* Ex. 99.1 to September 25, 2017 Form 6-K (emphasis added). Notably, in that same announcement, Defendant Odidi confirmed that he knew or should have known that the Rexista NDA would not be recommended for approval in its current form due to IPCI's failure to follow the 2015 FDA Guidance: "We had already planned the additional Category 2 and Category 3 studies the FDA has requested…." *Id*.

65. On January 24, 2018, IPCI stated that, after it received the CRL from the FDA, the Company "immediately began preparing its response, including finalizing protocols and plans to complete the Category 2 and 3 studies to support the application. The planned studies to support both the oral and intranasal route of abuse-deterrent label claims are scheduled to commence within the next few weeks and expected to be take approximately six months from commencement." *See* Ex. 99.1 to January 24, 2018 Form 6-K. These studies are necessary to comply with the 2015 FDA Guidance.

66. On December 5, 2017, the Company announced it had received written notification from NASDAQ "notifying the Company that the minimum bid price per share for its common shares was below $1.00 for a period of 30 consecutive business days and that the Company did not meet the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2)." *See* Ex. 99.1 to December 5, 2017 Form 6-K.

DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS DURING THE CLASS PERIOD

67. The Class Period begins on May 21, 2015, when IPCI filed a Form 6-K with the SEC attaching as Exhibit 99.1 a press release entitled "Intellipharmaceutics Intends to Accelerate its Rexista™ Oxycodone XR Development Program on the Basis of Positive Feedback from the FDA" (the "May 2015 Press Release"). In the May 2015 Press Release, Defendants stated, in part:

> [T]he United States Food and Drug Administration ("FDA") provided the Company with notification regarding its Investigational New Drug Application ("IND") submission for Rexista™ Oxycodone XR (Abuse Deterrent oxycodone hydrochloride) extended release tablets. The notification from the FDA stated that ***the Company will not be required to conduct Phase III studies if bioequivalence to Oxycontin™ is demonstrated***.
>
> * * * *
>
> ***The Company believes the FDA notification is significant as it provides a basis for an accelerated development plan for its Rexista™ Oxycodone XR product candidate, without the need for more costly and time-consuming Phase III studies***. The Company intends to file a New Drug Application ("NDA") for Rexista™ Oxycodone XR (Abuse Deterrent oxycodone hydrochloride) extended release tablets with the FDA within the next 6 to 12 months, although no assurance to this effect can be given. Further, there can be no assurance that the FDA will ultimately approve the NDA for sale of Rexista™ Oxycodone XR in the U.S. market, or that it will ever be successfully commercialized.
>
> "***We are thrilled with the FDA's positive acknowledgement, which enables us to accelerate the development and commercialization of our abuse deterrent Rexista™ Oxycodone XR product candidate***," stated Dr. Isa Odidi, CEO and co-founder of Intellipharmaceutics. "***The avoidance of a Phase III trial eliminates a***

> ***significant financial hurdle. More importantly, it shortens the development timeline and potential time to market.***"

(Emphasis added).

68. The foregoing statements were materially false and misleading when made because, *inter alia*, the Company did not conduct studies in accordance with the 2015 FDA Guidance, and thus, IPCI could not demonstrate bioequivalence to Oxycontin. Indeed, in voting against the propriety of labeling Rexista for abuse-deterrent properties for a single route without a complete assessment of all relevant routes of abuse, one committee member noted that without data from the recommended studies, "We don't know that there's bioequivalence for effect. And I could envision a situation where whatever, the blue dye or whatever it is, mixing with the oxycodone, when you take it, it's not going to give you the same amount of analgesic activity." Tr. 252:4-253:14.

69. On July 13, 2015, IPCI filed a Quarterly Report on Form 6-K with the SEC announcing the Company's financial and operating results for the quarter ended May 31, 2015 (the "Q2 2015 6-K"). The Q2 2015 6-K contained signed certifications by Defendants Odidi and Della Penna, stating that the financial information contained in the Q2 2015 6-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

70. In the Q2 2015 6-K, IPCI stated, in part:

> ***The Company believes, in light of previously announced results of the three definitive Phase I pharmacokinetic trials, that it will not be required to conduct Phase III studies, although no assurance to that effect can be given***. ***The Company believes the FDA notification is significant as it provides a basis for an accelerated development plan for its Rexista™ Oxycodone XR product candidate, without the need for more costly and time consuming Phase III studies***. The Company intends to file an NDA for Rexista™ Oxycodone XR (Abuse Deterrent oxycodone hydrochloride) extended release tablets with the FDA within the next 6 to 12 months, although no assurance to this effect can be given.

(Emphasis added).

71. The foregoing statements were materially false and misleading when made because, *inter alia*, the Company did not conduct studies in accordance with the 2015 FDA Guidance, and thus, IPCI could not demonstrate bioequivalence to Oxycontin. *See, e.g.*, Tr. 252:4-253:14.

72. On October 9, 2015, IPCI filed a Quarterly Report on Form 6-K with the SEC announcing the Company's financial and operating results for the quarter ended August 31, 2015 (the "Q3 2015 6-K"). The Q2 2015 6-K contained signed certifications by Defendants Odidi and Della Penna, stating that the financial information contained in the Q3 2015 6-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

73. In the Q3 2015 6-K, IPCI stated, in part:

> ***The Company believes, in light of previously announced results of the three definitive Phase I pharmacokinetic trials, that it will not be required to conduct Phase III studies, although no assurance to that effect can be given. The Company believes the FDA notification is significant as it provides a basis for an accelerated development plan for its Rexista™ Oxycodone XR product candidate, without the need for more costly and time consuming Phase III studies***. The Company intends to file an NDA for Rexista™ Oxycodone XR (Abuse Deterrent oxycodone hydrochloride) extended release tablets with the FDA within the next 6 to 12 months, although no assurance to this effect can be given.
>
> * * * *
>
> ***The formulation is intended to present a significant barrier to tampering when subjected to various forms of anticipated physical and chemical manipulation commonly used by abusers. It is also designed to prevent dose dumping when inadvertently co-administered with alcohol.*** Dose dumping is the rapid release of an active ingredient from a controlled-release drug into the blood stream that can result in increased toxicity, side effects, and a loss of efficacy. Dose dumping can result by consuming the drug through crushing, taking with alcohol, extracting with other beverages, vaporizing or injecting. ***In addition, when crushed or pulverized and hydrated, the proposed extended release formulation is designed to coagulate instantaneously and entrap the drug in a viscous hydrogel, which is intended to prevent syringing, injecting and snorting***.

(Emphasis added).

74. The foregoing statements were materially false and misleading when made because, *inter alia,* the Company did not conduct studies in accordance with the 2015 FDA Guidance, and thus, IPCI could not demonstrate bioequivalence to Oxycontin. *See, e.g.*, Tr. 252:4-253:14. Moreover, the foregoing statements were materially false and misleading when made because "***no clinical studies*** of the pharmacokinetic effects of manipulation or pharmacodynamic endpoints ***were conducted as recommended in the guidance***." Tr. 30:22-31:5 (emphasis added).

75. On October 15, 2015, IPCI filed a Form 6-K with the SEC attaching as Exhibit 99.1 a presentation entitled "The Future of Drug Delivery" given by Defendant Della Penna at the Dawson James Securities Growth Stock Conference in Jupiter, Florida that same day (the "October 2015 Presentation"); on March 15, 2016, IPCI filed a Form 6-K with the SEC attaching as Exhibit 99.1 a presentation entitled "The Future of Drug Delivery" given by Defendant Della Penna at the Roth Investor Conference in Newport Beach, California that same day (the "March 2016 Presentation"); and on September 13, 2016, IPCI filed a Form 6-K with the SEC attaching as Exhibit 99.1 a presentation entitled "The Future of Drug Delivery" given by Defendant Della Penna at the Rodman & Renshaw Global Investment Conference that same day (the "September 2016 Presentation"). In the October 2015 Presentation, the March 2016 Presentation, and the September 2016 Presentation, Defendant Della Penna displayed slides touting Rexista™'s "ABUSE DETERRENT ATTRIBUTES," including:

- Difficult to crush, pulverize, or extract with beverages/household solutions
- Designed to prevent Dose Dumping when co-administered with alcohol
- Coagulates instantaneously if crushed/pulverized and then hydrated
- Once hydrated, forms a viscous hydrogel that is difficult to:

- Syringe
- Inject
- Snort

- Abuse by grinding, chewing, licking, inhalation, snorting, and insufflation release a stigmatizing blue dye.
- Abuse by applying heat:
  - Difficult to vaporize without pyrolization.
  - Difficult to inhale from burning.

76. The foregoing statements were materially false and misleading when made because, *inter alia*, Defendants had no basis to assert that Rexista possessed the foregoing abuse deterrent "attributes," as they had not conducted the necessary studies in accordance with the 2015 FDA Guidance to support such claims. Indeed, the FDA Advisory Committee noted that "***no clinical studies*** of the pharmacokinetic effects of manipulation or pharmacodynamic endpoints ***were conducted as recommended in the guidance***." Tr. 30:22-31:5 (emphasis added). The foregoing statements were also materially false and misleading when made because Defendants did not have data to support claims that Rexista's excipients (a nasal irritant and blue dye) deterred abuse by the nasal and oral routes.

77. On January 14, 2016, IPCI filed a Form 6-K with the SEC attaching as Exhibit 99.1 a press release entitled "Intellipharmaceutics Announces Successful Bioequivalence Results for Abuse Deterrent Rexista™ Oxycodone XR" (the "January 2016 Press Release"). In the January 2016 Press Release, Defendants stated, in part:

> "*We take great pride in being the first pharmaceutical company, to the best of our knowledge, to have demonstrated bioequivalence in both fasted and fed conditions to the brand reference drug Oxycontin®.* ***This enables us to accelerate the development and commercialization of our abuse deterrent Rexista™ Oxycodone XR product candidate without the need for costly and time-consuming Phase III efficacy trials***," stated Dr. Isa Odidi, CEO and co-founder of Intellipharmaceutics. "*We look forward to filing an NDA within the next six*

months, which we hope will lead to a positive contribution in addressing an unmet need in opioid abuse and addiction."

(Emphasis added).

78. The foregoing statements were materially false and misleading when made because, *inter alia*, the Company did not conduct studies in accordance with the 2015 FDA Guidance, and thus, IPCI could not demonstrate bioequivalence to Oxycontin. *See, e.g.*, Tr. 252:4-253:14. Additionally, Defendants had no reason to believe that the filing of the Rexista NDA would lead to a positive contribution because the 2015 FDA Guidance was not followed: "***The panel believes, and I believe, that the guidelines need to be followed. I think the committee feels uncomfortable in providing a signal that it's all right to present incomplete data and expect a positive outcome***." Tr. 261:15-262:3 (emphasis added).

79. On February 29, 2016, IPCI filed an Annual Report on Form 6-K with the SEC announcing the Company's financial and operating results for the year ended November 30, 2015 (the "2015 6-K"). The 2015 6-K contained signed certifications by Defendants Odidi and Della Penna, stating that the financial information contained in the 2015 6-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

80. In the 2015 6-K, IPCI stated, in part:

> ***The formulation is intended to present a significant barrier to tampering when subjected to various forms of physical and chemical manipulation commonly used by abusers.*** It is also designed to prevent dose dumping when inadvertently co-administered with alcohol. Dose dumping is the rapid release of an active ingredient from a controlled-release drug into the blood stream that can result in increased toxicity, side effects, and a loss of efficacy. Dose dumping can result by consuming the drug through crushing, taking with alcohol, extracting with other beverages, vaporizing or injecting. ***In addition, when crushed or pulverized and hydrated, the proposed extended release formulation is designed to coagulate instantaneously and entrap the drug in a viscous hydrogel, which is intended to prevent syringing, injecting and snorting. Our Rexista TM Oxycodone XR formulation contains a blue dye that is emitted once the tablet is tampered with***

> ***or crushed. This stigmatizing blue dye acts as a deterrent if abused orally or via the intra-nasal route.***
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> * * * *
>
> ***The FDA notification is significant as it provides a basis for an accelerated development plan for our Rexista™ Oxycodone XR product candidate, without the need for more costly and time consuming Phase III studies. We are continuing to work towards satisfying the requirements to file an NDA for Rexista™ Oxycodone XR (abuse deterrent oxycodone hydrochloride) extended release tablets with the FDA*** and plan to complete this filing within the next six months, although there can be no assurances that we will be successful in filing an NDA for Rexista™ Oxycodone XR in six months' time.

(Emphasis added).

81. The foregoing statements were materially false and misleading when made because, *inter alia*, the Company did not conduct studies in accordance with the 2015 FDA Guidance, and thus, IPCI could not demonstrate bioequivalence to Oxycontin. *See, e.g.*, Tr. 252:4-253:14. The foregoing statements were also materially false and misleading when made because "***no clinical studies*** of the pharmacokinetic effects of manipulation or pharmacodynamic endpoints ***were conducted as recommended in the guidance***," Tr. 30:22-31:5 (emphasis added), and because Defendants did not have data to support claims that Rexista's excipients (a nasal irritant and blue dye) deterred abuse by the nasal and oral routes.

82. On March 1, 2016, IPCI filed an Annual Information Form on Form 6-K with the SEC describing the Company's financial and operations results for the year ending November 30, 2015 in the context of its historical and possible future development (the "2015 AIF"). The 2015 AIF contained signed certifications by Defendants Odidi and Della Penna, stating that the financial information contained in the 2015 AIF was accurate and disclosed any material changes to the Company's internal control over financial reporting.

83. In the 2015 AIF, IPCI stated, in part:

> ***The formulation is intended to present a significant barrier to tampering when subjected to various forms of physical and chemical manipulation commonly used by abusers. It is also designed to prevent dose dumping when inadvertently co-administered with alcohol. Dose dumping is the rapid release of an active ingredient from a controlled-release drug into the blood stream that can result in increased toxicity, side effects, and a loss of efficacy.*** Dose dumping can result by consuming the drug through crushing, talking with alcohol, extracting with other beverages, vaporizing or injecting. In addition, when crushed or pulverized and hydrated, the proposed extended release formulation is designed to coagulate instantaneously and entrap the drug in a viscous hydrogel, which is intended to prevent syringing, injecting and snorting. ***Our Rexista Oxycodone XR formulation contains a blue dye that is emitted once the tablet is tampered with or crushed. The stigmatizing blue dye acts as a deterrent if abused orally or via the intra-nasal route.***
>
> * * * *
>
> ***Having now demonstrated such bioequivalence, we believe we will not be required to conduct Phase III studies although no assurance can be given that we will not be required to conduct further studies for Rexista Oxycodone XR. The FDA notification is significant as it provides a basis for an accelerated development plan for our Rexista Oxycodone XR product candidate, without the need for more costly and time consuming Phase III studies. We are continuing to work towards satisfying the requirements to file an NDA for Rexista Oxycodone XR (an abuse deterrent oxycodone hydrochloride) extended release tables with the FDA*** and plan to complete this filing within the next six months, although there can be no assurances that we will be successful in filing an NDA for Rexista Oxycodone XR in six months' time.

(Emphasis added).

84. The foregoing statements were materially false and misleading when made because, *inter alia*, the Company did not conduct studies in accordance with the 2015 FDA Guidance, and thus, IPCI could not demonstrate bioequivalence to Oxycontin. *See, e.g.*, Tr. 252:4-253:14. The foregoing statements were also materially false and misleading when made because "***no clinical studies*** of the pharmacokinetic effects of manipulation or pharmacodynamic endpoints ***were conducted as recommended in the guidance***," Tr. 30:22-31:5 (emphasis added), and because Defendants did not have data to support claims that Rexista's excipients (a nasal irritant and blue dye) deterred abuse by the nasal and oral routes.

85. On March 21, 2016, IPCI filed an Annual Report on Form 20-F with the SEC describing the Company's financial and operations results for the year ending November 30, 2015 (the "2015 20-F"). The 2015 20-F contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Isa and Della Penna, stating that the financial information contained in the 2015 20-F was accurate and disclosed any material changes to the Company's internal control over financial reporting.

86. In the 2015 20-F, IPCI stated, in part:

> ***The formulation is intended to present a significant barrier to tampering when subjected to various forms of physical and chemical manipulation commonly used by abusers. It is also designed to prevent dose dumping when inadvertently co-administered with alcohol***. Dose dumping is the rapid release of an active ingredient from a controlled-release drug into the blood stream that can result in increased toxicity, side effects, and a loss of efficacy. Dose dumping can result by consuming the drug through crushing, talking with alcohol, extracting with other beverages, vaporizing or injecting. In addition, when crushed or pulverized and hydrated, the proposed extended release formulation is designed to coagulate instantaneously and entrap the drug in a viscous hydrogel, which is intended to prevent syringing, injecting and snorting. ***Our Rexista Oxycodone XR formulation contains a blue dye that is emitted once the tablet is tampered with or crushed. The stigmatizing blue dye acts as a deterrent if abused orally or via the intra-nasal route***.
>
> * * * *
>
> Having now demonstrated such bioequivalence, we believe we will not be required to conduct Phase III studies although no assurance can be given that we will not be required to conduct further studies for Rexista Oxycodone XR. ***The FDA notification is significant as it provides a basis for an accelerated development plan for our Rexista Oxycodone XR product candidate, without the need for more costly and time consuming Phase III studies. We are continuing to work towards satisfying the requirements to file an NDA for Rexista Oxycodone XR (an abuse deterrent oxycodone hydrochloride) extended release tables with the FDA*** and plan to complete this filing within the next six months, although there can be no assurances that we will be successful in filing an NDA for Rexista Oxycodoen XR in six months' time.
>
> * * * *

> We will be required by the FDA to comply with NDA procedures for our branded products prior to commencement of marketing by us or our licensees. New drug compounds and new formulations for existing drug compounds which cannot be filed as ANDAs are subject to NDA procedures. These procedures include (a) preclinical laboratory and animal toxicology tests; (b) scaling and testing of production batches; (c) submission of an IND, and subsequent approval is required before any human clinical trials can commence; (d) adequate and well controlled replicate human clinical trials to establish the safety and efficacy of the drug for its intended indication; (e) the submission of an NDA to the FDA; and (f) FDA approval of an NDA prior to any commercial sale or shipment of the product, including pre-approval and post-approval inspections of our manufacturing and testing facilities. If all of this data in the product application is owned by the applicant, the FDA will issue its approval without regard to patent rights that might be infringed or exclusivity periods that would affect the FDA's ability to grant an approval if the application relied upon data which the applicant did not own. ***We intend to generate all data necessary to support FDA approval of the applications we file***.

(Emphasis added).

87. The foregoing statements were materially false and misleading when made because, *inter alia*, the Company did not conduct studies in accordance with the 2015 FDA Guidance, and thus, IPCI could not demonstrate bioequivalence to Oxycontin. *See, e.g.*, Tr. 252:4-253:14. The foregoing statements were also materially false and misleading when made because "***no clinical studies*** of the pharmacokinetic effects of manipulation or pharmacodynamic endpoints ***were conducted as recommended in the guidance***," Tr. 30:22-31:5 (emphasis added), and because Defendants did not have data to support claims that Rexista's excipients (a nasal irritant and blue dye) deterred abuse by the nasal and oral routes. Finally, IPCI's statement that it "intend[ed] to generate all data necessary to support FDA approval" of its NDA applications was materially false and misleading when made because Defendants did not conduct all studies in accordance with the 2015 FDA Guidance. In fact, one committee member stated, "***The panel believes, and I believe, that the guidelines need to be followed***. ***I***

think the committee feels uncomfortable in providing a signal that it's all right to present incomplete data and expect a positive outcome." Tr. 261:15-262:3 (emphasis added).

88. On April 15, 2016, July 13, 2016, and October 14, 2016, IPCI filed Quarterly Reports on Form 6-K with the SEC announcing the Company's financial and operating results for the quarters ended February 29, 2016 (the "Q1 2016 6-K"), May 31, 2016 (the "Q2 2016 6-K"), and August 31, 2016 (the "Q3 2016 6-K"). The Q1 2016 6-K, Q2 2016 6-K, and Q3 2016 6-K contained signed certifications by Defendants Odidi and Della Penna, stating that the financial information contained in the Q1 2016 6-K, Q2 2016 6-K, and Q3 2016 6-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

89. In the Q1 2016 6-K, Q2 2016 6-K, and Q3 2016 6-K, IPCI stated, in part:

> ***The formulation is intended to present a significant barrier to tampering when subjected to various forms of physical and chemical manipulation commonly used by abusers. It is also designed to prevent dose dumping when inadvertently co-administered with alcohol***. Dose dumping is the rapid release of an active ingredient from a controlled-release drug into the blood stream that can result in increased toxicity, side effects, and a loss of efficacy. Dose dumping can result by consuming the drug through crushing, talking with alcohol, extracting with other beverages, vaporizing or injecting. ***In addition, when crushed or pulverized and hydrated, the proposed extended release formulation is designed to coagulate instantaneously and entrap the drug in a viscous hydrogel, which is intended to prevent syringing, injecting and snorting. Our Rexista Oxycodone XR formulation contains a blue dye that is emitted once the tablet is tampered with or crushed. The stigmatizing blue dye acts as a deterrent if abused orally or via the intra-nasal route.***

(Emphasis added).

90. The foregoing statements were materially false and misleading when made because, *inter alia*, Defendants had not conducted all studies in accordance with the 2015 FDA Guidance necessary to demonstrate that the Company's formulation of Rexista possessed the foregoing abuse-deterrent properties. The foregoing statements were also materially false and

misleading when made because Defendants did not have data to support claims that Rexista's excipients (a nasal irritant and blue dye) deterred abuse by the nasal and oral routes.

91. On May 11, 2016, Defendant Della Penna gave an interview to *Streetwise Reports* in which he stated, in part:

> ***[W]e believe Rexista™ has a number of abuse-deterrent properties that not only match but exceed those of both currently marketed products and products in late-stage development. These properties address mitigating abuse via methods of tampering, such as crushing, chewing, melting, and cooking, and via methods of administration, such as snorting, injecting, smoking, dose dumping with alcohol, and abuse via heat extraction***.
>
> * * * *
>
> ***Rexista™ also contains a stigmatizing blue dye that is emitted once the tablet is tampered with or crushed. This blue dye acts as a deterrent if abused orally or via the intranasal route; it is not easily washed away. An abuser will be reluctant to tamper with Rexista™ oxycodone given this stigmatizing effect***.
>
> * * * *
>
> While there are only a handful of opioids that have abuse-deterrent formulations (AD or ADFs) in market today, some have not performed well because they are limited in their breadth of abuse-deterrent properties. Abusers are quite resourceful: If you lock the front door they will try the back door, the window, etc. The product must be robust enough to anticipate the different abuse routes available. ***We believe Rexista™ has a full suite of AD properties that will make it difficult to abuse by crushing, chewing, snorting, injecting, heating or co-administering with alcohol/solvents***. The more difficult you make it, the greater the deterrence factor.

(Emphasis added).

92. The foregoing statements were materially false and misleading when made because, *inter alia*, there was no reasonable basis to "believe" that IPCI's formulation of Rexista possessed the foregoing abuse-deterrent properties because Defendants had not conducted all studies in accordance with the 2015 FDA Guidance to support such claims.

93. On July 5, 2016, IPCI filed a Form 6-K with the SEC attaching as Exhibit 99.1 a press release entitled "Intellipharmaceutics Reports Updated on Rexista™ XR: FDA Grants Waiver of NDA Filing Fee, and Topline Pharmacokinetcis Results Indicate No Food Effect" (the "July 2016 Press Release"). In the July 2016 Press Release, Defendants stated, in part:

> ***The formulation is intended to present a significant barrier to tampering when subjected to various forms of physical and chemical manipulation commonly used by abusers. It is also designed to prevent dose dumping when inadvertently co-administered with alcohol***. Dose dumping is the rapid release of an active ingredient from a controlled-release drug into the blood stream that can result in increased toxicity, side effects, and a loss of efficacy. Dose dumping can result by consuming the drug through crushing, taking with alcohol, extracting with other beverages, vaporizing or injecting. ***In addition, when crushed or pulverized and hydrated, the proposed extended release formulation is designed to coagulate instantaneously and entrap the drug in a viscous hydrogel, which is intended to prevent syringing, injecting and snorting. Our Rexista TM XR formulation contains a blue dye that is emitted once the tablet is tampered with or crushed. The blue dye will stain mucous membranes and skin if the product is manipulated and comes in contact with moisture. This stigmatizing blue dye is intended to act as a visible deterrent against inappropriate use if abused orally or via the intra-nasal route.***

(Emphasis added).

94. The foregoing statements were materially false and misleading when made because, *inter alia*, Defendants had not conducted all studies in accordance with the 2015 FDA Guidance necessary to demonstrate that the Company's formulation of Rexista possessed the foregoing abuse-deterrent properties. The foregoing statements were also materially false and misleading when made because Defendants did not have data to support claims that Rexista's excipients (a nasal irritant and blue dye) deterred abuse by the nasal and oral routes.

95. On November 25, 2016, IPCI filed a Form 6-K with the SEC attaching as Exhibit 99.1 a press release entitled "Intellipharmaceutics Submits New Drug Application for Rexista® (oxycodone hydrochloride extended release), an Abuse Deterrent Opioid Analgesic for the

Treatment of Moderate to Severe Pain" (the "November 2016 Press Release"). In the November 2016 Press Release, Defendants stated, in part:

> ***The submission also includes a comprehensive array of abuse-deterrent studies conducted to support abuse-deterrent label claims related to abuse of drug by oral, intra-nasal and intravenous pathways, having reference to the FDA's "Abuse-Deterrent Opioids – Evaluation and Labelling" guidance published in April 2015***.
>
> ***The abuse-deterrent properties incorporated into Rexista® are designed to make the product unlikable and discourage or make it more difficult to manipulate for the purpose of abuse or misuse via common routes of administration including: ingestion following chewing, licking or crushing; insufflation; inhalation; or injection***. If approved, Rexista® may be the only abuse-deterrent oxycodone product with properties that may provide early warning of drug abuse if the product is manipulated or abused. The Company previously announced the results of a food effect study which showed that Rexista® can be administered with or without a meal (i.e., no food effect), providing another point of differentiation from currently marketed oral oxycodone extended release products.
>
> * * * *
>
> The CEO of Intellipharmaceutics, Dr. Isa Odidi, said, "*The NDA submission of Rexista represents a critical milestone and turning point for the Company.* ***This is our first NDA submission and the first abuse-deterrent oxycodone product candidate we are aware of that not only resists common forms of abuse but provides a preventative tool that may flag early warning of abuse***. *We are excited about the prospect of Rexista, if approved, having a positive impact in addressing the opioid epidemic.* ***We believe our suite of abuse-deterrent and overdose prevention technologies are best in class*** *and we look forward to further expanding our development program for abuse-deterrent pain and other medications. The Company has identified potential manufacturing partners and is currently evaluating various manufacturing options for Rexista in the U.S. We look forward to working with the FDA during their review of our NDA submission.*"

(Emphasis added).

96. The foregoing statements were materially false and misleading when made because, *inter alia*, Defendants did not follow the 2015 FDA Guidance because IPCI submitted only Category 1 (in vitro) studies to support labeling of Rexista for abuse deterrence, and it also

sought labeling for abuse-deterrent properties only for the IV route of abuse and not also for the nasal and oral routes of abuse, when the 2015 FDA Guidance recommends that evaluation of an abuse-deterrent formulation should take into consideration the known routes of abuse such as oral, intranasal, and IV abuse. Moreover, in accordance with the 2015 FDA Guidance, IPCI should have conducted Category 2 and 3 studies because they provide important information for the evaluation of abuse deterrent formulations with respect to oral and intranasal abuse that cannot be derived from Category 1 studies alone.

97. On February 2, 2017, IPCI filed a Form 6-K with the SEC attaching as Exhibit 99.1 a press release entitled "Intellipharmaceutics Announces FDA Acceptance for Filing of NDA for Rexista™ (oxycodone hydrochloride extended release), an Abuse Deterrent Analgesic for the Treatment of Moderate to Severe Pain" (the "February 2017 Press Release"). In the February 2017 Press Release, Defendants stated, in part:

> ***The submission also includes abuse-deterrent studies conducted to support abuse-deterrent label claims related to abuse of the drug by various pathways, including oral, intra-nasal and intravenous, having reference to the FDA's "Abuse-Deterrent Opioids —Evaluation and Labelling" guidance published in April 2015***.
>
> * * * *
>
> ***The abuse-deterrent properties incorporated into Rexista TM are designed to make the product unlikable and discourage or make it more difficult to manipulate for the purpose of abuse or misuse via common routes of administration including: ingestion following chewing, licking or crushing; insufflation; inhalation; or injection. If approved, Rexista TM may be the only abuse-deterrent oxycodone product with properties that may provide early warning of drug abuse if the product is manipulated or abused***. The Company previously announced the results of a food effect study which showed that Rexista TM can be administered with or without a meal (i.e., no food effect), providing another point of differentiation from currently marketed oral oxycodone extended release products.
>
> * * * *

> The CEO of Intellipharmaceutics, Dr. Isa Odidi, said, "***The acceptance of filing of our NDA for Rexista represents an important step towards the commercialization of a potentially best-in-class abuse-deterrent oxycodone hydrochloride extended release product***. *We look forward to working with the FDA during their review of our NDA submission.*

(Emphasis added).

98. The foregoing statements were materially false and misleading when made because, *inter alia*, Defendants did not follow the 2015 FDA Guidance because IPCI submitted only Category 1 (in vitro) studies to support labeling of Rexista for abuse deterrence, and it also sought labeling for abuse-deterrent properties only for the IV route of abuse and not also for the nasal and oral routes of abuse, when the 2015 FDA Guidance recommends that evaluation of an abuse-deterrent formulation should take into consideration the known routes of abuse such as oral, intranasal, and IV abuse.

99. On February 10, 2017, IPCI filed an Annual Report on Form 6-K with the SEC announcing the Company's financial and operating results for the year ended November 30, 2016 (the "2016 6-K"). The 2015 6-K contained signed certifications by Defendants Isa Odidi and Della Penna, stating that the financial information contained in the 2016 6-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

100. In the 2016 6-K, IPCI stated, in part:

> ***The submission also includes abuse-deterrent studies conducted to support abuse-deterrent label claims related to abuse of the drug by various pathways, including oral, intra-nasal and intravenous, having reference to the FDA's "Abuse-Deterrent Opioids — Evaluation and Labelling" guidance published in April 2015***.

(Emphasis added).

101. The foregoing statements were materially false and misleading when made because, *inter alia*, Defendants did not follow the 2015 FDA Guidance because IPCI submitted

only Category 1 (in vitro) studies to support labeling of Rexista for abuse deterrence, and it also sought labeling for abuse-deterrent properties only for the IV route of abuse and not also for the nasal and oral routes of abuse, when the 2015 FDA Guidance recommends that evaluation of an abuse-deterrent formulation should take into consideration the known routes of abuse such as oral, intranasal, and IV abuse.

102. On February 28, 2017, IPCI filed an Annual Information Form on Form 6-K and an Annual Report on Form 20-F with the SEC describing the Company's financial and operations results for the year ending November 30, 2016 in the context of its historical and possible future development (the "2016 AIF" and "2016 20-F")). The 2016 AIF contained signed certifications by Defendants Odidi and Della Penna, stating that the financial information contained in the 2016 AIF was accurate and disclosed any material changes to the Company's internal control over financial reporting, and the 2016 20-F contained signed certifications pursuant to SOX by Defendants Odidi and Della Penna, stating that the financial information contained in the 2016 20-F was accurate and disclosed any material changes to the Company's internal control over financial reporting. Moreover, on April 12, 2017, IPCI filed a Quarterly Report on Form 6-K with the SEC announcing the Company's financial and operating results for the quarter ended February 28, 2017 (the "Q1 2017 6-K"). The Q1 2017 6-K contained signed certifications by Defendants Odidi and Della Penna, stating that the financial information contained in the Q1 2017 6-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

103. In the 2016 AIF, the 2016 20-F, and the Q1 2017 6-K, IPCI stated, in part:

> The submission is supported by pivotal pharmacokinetic studies that demonstrated that Rexista is bioequivalent to OxyContin (oxycodone hydrochloride extended release). ***The submission also includes abuse-deterrent studies conducted to support abuse-deterrent label claims related to abuse of the***

drug by various pathways, including oral, intra-nasal and intravenous, having reference to the FDA's "Abuse-Deterrent Opioids - Evaluation and Labeling" guidance published in April 2015.

* * * *

The formulation is intended to present a significant barrier to tampering when subjected to various forms of physical and chemical manipulation commonly used by abusers. It is also designed to prevent dose dumping when inadvertently co-administered with alcohol. Dose dumping is the rapid release of an active ingredient from a controlled-release drug into the blood stream that can result in increased toxicity, side effects, and a loss of efficacy. Dose dumping can result by consuming the drug through crushing, taking with alcohol, extracting with other beverages, vaporizing or injecting. ***In addition, when crushed or pulverized and hydrated, the proposed extended release formulation is designed to coagulate instantaneously and entrap the drug in a viscous hydrogel, which is intended to prevent syringing, injecting and snorting. Our Rexista TM formulation is difficult to abuse through the application of heat or an open flame, making it difficult to inhale the active ingredient from burning. Our Rexista TM formulation contains a blue dye that is emitted once the tablet is tampered with or crushed. This stigmatizing blue dye may act as a deterrent if abused orally or via the intra-nasal route and may also serve as an early warning mechanism to flag potential misuse or abuse***.

(Emphasis added).

104. The foregoing statements were materially false and misleading when made because, *inter alia*, Defendants did not follow the 2015 FDA Guidance because IPCI submitted only Category 1 (in vitro) studies to support labeling of Rexista for abuse deterrence, and it also sought labeling for abuse-deterrent properties only for the IV route of abuse and not also for the nasal and oral routes of abuse, when the 2015 FDA Guidance recommends that evaluation of an abuse-deterrent formulation should take into consideration the known routes of abuse such as oral, intranasal, and IV abuse. The foregoing statements were also materially false and misleading when made because, *inter alia*, the Company did not conduct studies in accordance with the 2015 FDA Guidance, and thus, IPCI could not demonstrate bioequivalence to Oxycontin. *See, e.g.*, Tr. 252:4-253:14. Finally, the foregoing statements were materially false

and misleading when made because Defendants did not have data to support claims that Rexista's excipients (a nasal irritant and blue dye) deterred abuse by the nasal and oral routes.

105. In May 2017, an analyst at Dawson James Securities held a "fireside chat" with "Intellipharmaceutics management" to "get an update on various Company developments," including the status of the Rexista filing. *See* May 5, 2017 Dawson James Securities Company Update. During the fireside chat, the IPCI's management reiterated that it was the Company's "goal to receive ***all three allowable deterrent claims for Rexista, which would be a significant market differentiator.***" *Id*. (emphasis added).

106. The foregoing statements were materially false and misleading when made because the Company, in truth, did not follow the 2015 FDA Guidance because IPCI submitted only Category 1 (in vitro) studies to support labeling of Rexista for abuse deterrence related to only the IV route of abuse, when IPCI should have conducted a complete abuse-deterrent assessment to cover multiple routes of administration such as oral, intranasal, and IV abuse, and should have conducted Category 2 and 3 studies because they provide important information for the evaluation of abuse deterrent formulations with respect to oral and intranasal abuse that cannot be derived from Category 1 studies alone.

107. On June 30, 2017, IPCI filed a Form 6-K with the SEC attaching as Exhibit 99.1 a press release entitled "Intellipharmaceutics Announces FDA Advisory Committee Meeting for Rexista™ (oxycodone hydrochloride extended release), an Abuse Deterrent Opioid Analgesic for the Treatment of Moderate to Severe Pain" (the "June 2017 Press Release"). In the June 2017 Press Release, Defendants stated, in part:

> The submission is supported by pivotal pharmacokinetic studies that demonstrated that Rexista is bioequivalent to OxyContin (oxycodone hydrochloride extended release). ***The submission also includes abuse-deterrent studies conducted to support abuse-deterrent label claims related to abuse of the***

> ***drug by various pathways, including oral, intra-nasal and intravenous, having reference to the FDA's "Abuse-Deterrent Opioids Evaluation and Labeling" guidance published in April 2015***.
>
> * * * *
>
> Our Rexista (abuse deterrent oxycodone hydrochloride extended release tables) NDA product candidate is intended as an abuse and alcohol-deterrent controlled-release oral formulation of oxycodone hydrochloride for the relief of pain. ***The Rexista long-acting formulation of oxycodone is intended to present a significant barrier to tampering when subjected to various forms of physical and chemical manipulation commonly used by abusers. It is also designed to prevent dose dumping when inadvertently co-administered with alcohol.*** Dose dumping is the rapid release of an active ingredient from a controlled-release drug into the blood stream that can result in increased toxicity, side effects, and a loss of efficacy. Dose dumping can result by consuming the drug through crushing, taking with alcohol, extracting with other beverages, vaporizing or injecting. ***In addition, when crushed or pulverized and hydrated, the proposed extended release formulation is designed to coagulate instantaneously and entrap the drug in a viscous hydrogel, which is intended to prevent syringing, injecting and snorting. Our Rexista formulation is difficult to abuse through the application of hear or an open flame, making it difficult to inhale the active ingredient from burning. Our Rexista formulation contains a blue dye that is emitted once the tablet is tampered with or crushed, and may act as a deterrent to a user who attempts to abuse it orally or via the intra-nasal route***.

(Emphasis added).

108. The foregoing statements were materially false and misleading when made because, *inter alia*, Defendants did not follow the 2015 FDA Guidance because IPCI submitted only Category 1 (in vitro) studies to support labeling of Rexista for abuse deterrence, and it also sought labeling for abuse-deterrent properties only for the IV route of abuse and not also for the nasal and oral routes of abuse, when the 2015 FDA Guidance recommends that evaluation of an abuse-deterrent formulation should take into consideration the known routes of abuse such as oral, intranasal, and IV abuse. The foregoing statements were also materially false and misleading when made because, *inter alia*, the Company did not conduct studies in accordance with the 2015 FDA Guidance, and thus, IPCI could not demonstrate bioequivalence to

Oxycontin. *See* Tr. 252:4-253:14. Finally, the foregoing statements were materially false and misleading when made because Defendants did not have data to support claims that Rexista's excipients (a nasal irritant and blue dye) deterred abuse by the nasal and oral routes.

109. On July 11, 2017, IPCI filed a Quarterly Report on Form 6-K with the SEC announcing the Company's financial and operating results for the quarter ended May 31, 2017 (the "Q2 2017 6-K"). The Q2 2017 6-K contained signed certifications by Defendants Odidi and Della Penna, stating that the financial information contained in the Q2 2017 6-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

110. In the Q2 2017 6-K, IPCI stated, in part:

> ***The submission also includes abuse-deterrent studies conducted to support abuse-deterrent label claims, having reference to the FDA's "Abuse-Deterrent Opioids — Evaluation and Labeling" guidance published in April 2015. The abuse-deterrent properties incorporated into Rexista TM are designed to make the product unlikable and discourage or make it more difficult to manipulate for the purpose of abuse or misuse***, and the Company is preparing to share its data with the Advisory Committees as a key step towards securing FDA approval of Rexista TM.
>
> * * * *
>
> ***The formulation is intended to present a significant barrier to tampering when subjected to various forms of physical and chemical manipulation commonly used by abusers. It is also designed to prevent dose dumping when inadvertently co-administered with alcohol***. Dose dumping is the rapid release of an active ingredient from a controlled-release drug into the blood stream that can result in increased toxicity, side effects, and a loss of efficacy. Dose dumping can result by consuming the drug through crushing, taking with alcohol, extracting with other beverages, vaporizing or injecting. ***In addition, when crushed or pulverized and hydrated, the proposed extended release formulation is designed to coagulate instantaneously and entrap the drug in a viscous hydrogel, which is intended to prevent syringing, injecting and snorting. Our Rexista TM formulation is difficult to abuse through the application of heat or an open flame, making it difficult to inhale the active ingredient from burning. Our Rexista TM formulation contains a blue dye that is emitted once the tablet is tampered with or crushed. This stigmatizing blue dye may act as a deterrent if abused orally or via the intra-nasal route and may also serve as an early warning mechanism to flag potential misuse or abuse***.

* * * *

> ***The submission also includes abuse-deterrent studies conducted to support abuse-deterrent label claims related to abuse of the drug by various pathways, including oral, intra-nasal and intravenous, having reference to the FDA's "Abuse-Deterrent Opioids - Evaluation and Labeling" guidance published in April 2015***.

(Emphasis added).

111. The foregoing statements were materially false and misleading when made because, *inter alia*, Defendants did not follow the 2015 FDA Guidance because IPCI submitted only Category 1 (in vitro) studies to support labeling of Rexista for abuse deterrence, and it also sought labeling for abuse-deterrent properties only for the IV route of abuse and not also for the nasal and oral routes of abuse, when the 2015 FDA Guidance recommends that evaluation of an abuse-deterrent formulation should take into consideration the known routes of abuse such as oral, intranasal, and IV abuse. The foregoing statements were also materially false and misleading when made because, *inter alia*, the Company did not conduct studies in accordance with the 2015 FDA Guidance, and thus, IPCI could not demonstrate bioequivalence to Oxycontin. *See* Tr. 252:4-253:14. Finally, the foregoing statements were materially false and misleading when made because Defendants did not have data to support claims that Rexista's excipients (a nasal irritant and blue dye) deterred abuse by the nasal and oral routes.

THE TRUTH IS REVEALED

112. On July 24, 2017, in advance of the July 26th FDA Advisory Committee meeting, the FDA released a report that expressed serious concern about the adequacy of the information submitted by IPCI related to its Rexista NDA. The report stated, in part:

> "***The safety information collected in the pharmacokinetic studies was of limited value*** due to the fact that these were generally single-dose studies (except one multiple dose study) conducted in healthy volunteers who were naltrexone

> blocked. ***There were no human abuse liability studies submitted with the NDA***. ***No new safety signals were identified*** during the review of the oxycodone ER tablets application beyond what is already known for oxycodone products."

(Emphasis added).

113. As a result of these partial revelations of the true facts, the price of shares of IPCI's common stock fell, on heavy trading volume, from an opening price of $2.80 on July 24, 2017, to close at $2.42 at the end of trading on that same day. This drop of $0.38 represented a decline of approximately 14%.

114. On July 27, 2017, before the market opened, IPCI issued a press release, also attached as Exhibit 99.1 to a Form 6-K filed with the SEC, which announced an update on the FDA Advisory Committee meeting for Rexista. The press release stated:

> **Intellipharmaceutics Provides Update on FDA Advisory Committees Meeting for Rexista™ (oxycodone hydrochloride extended release), an Abuse-Deterrent Opioid Analgesic for the Treatment of Moderate to Severe Pain**
>
> TORONTO, July 26, 2017 (GLOBE NEWSWIRE) – Intellipharmaceutics International Inc. (Nasdaq:IPCI) (TSX:IPCI) ("Intellipharmaceutics" or the "Company"), a pharmaceutical company specializing in the research, development and manufacture of novel and generic controlled-release and targeted-release oral solid dosage drugs, today announced that the Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee of the U.S. Food and Drug Administration ("FDA") ***voted 22 to 1 in finding that the Company's New Drug Application ("NDA") for Rexista™ abuse-deterrent oxycodone hydrochloride extended release tablets should not be approved at this time***. ***The committees also voted 19 to 4 that the Company has not demonstrated that Rexista™ has properties that can be expected to deter abuse by the intravenous route of administration, and 23 to 0 that there are not sufficient data for Rexista™ to support inclusion of language regarding abuse-deterrent properties in the product label for the intravenous route of administration***.
>
> The committees expressed a desire to review the additional safety and efficacy data for RexistaTM that may be obtained from human abuse potential studies for the oral and intranasal routes of administration. ***Accordingly, the Company intends to conduct Category 3 abuse potential studies to provide the data the Company believes necessary to support abuse-deterrent properties of RexistaTM***

> ***for the oral and intranasal routes, which are required for abuse-deterrent labeling claims for such routes***. The Company has an FDA approved protocol for a human abuse potential study for the intranasal route of abuse, which it plans on commencing in the coming weeks.
>
> RexistaTM is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The FDA is not bound by the advisory committees' recommendation, but will consider their guidance as it continues its review of RexistaTM. The FDA set a Prescription Drug User Fee Act (PDUFA) goal date of September 25, 2017 for completion of its review of our RexistaTM NDA candidate.
>
> The CEO of Intellipharmaceutics, Dr. Isa Odidi, said, "***While we are disappointed with the Committees' overall vote, we will endeavor to remedy the concerns raised by completing the necessary human abuse potential studies in relation to the intranasal and oral routes of abuse***. We will continue to work with the FDA in progressing this file over the next few weeks as we approach the September 25, 2017 PDUFA date."

(Emphasis added).

115. As a result of these revelations of the true facts, the price of shares of IPCI's common stock again fell sharply, on heavy trading volume, from $2.49 per share at close on July 26, 2017, to close at $1.36 per share on July 27, 2017. This drop of $1.13 represented a substantial decline of over 45%.

SCIENTER ALLEGATIONS

A. The Company Knowingly Failed to Comply with the 2015 FDA Guidance, and thus Knew or Should Have Known that the Rexista NDA Would Not Be Approved

116. On November 25, 2016, when IPCI announced that it filed an NDA for Rexista, the Company assured investors (and continued to assure them thereafter) that its NDA submission was supported by "a comprehensive array of abuse-deterrent studies conducted to support abuse-deterrent label claims related to abuse of drug by oral, intra-nasal ***and*** intravenous pathways, having reference to the FDA's "Abuse-Deterrent Opioids – Evaluation and Labelling" guidance published in April 2015." *See, e.g.*, Form 6-K Press Release dated November 25, 2016

(emphasis added). In fact, Defendants explicitly stated, "***We intend to generate all data necessary to support FDA approval of the applications we file***." *See* 2015 20-F (emphasis added). Moreover, the FDA Advisory Committee confirmed that the FDA did not indicate to IPCI that approval could be obtained without following the 2015 FDA Guidance: "No, we provide advice that's consistent with the guidance." *See* Tr. 249:13-250:17. Therefore, there can be no doubt that Defendants knew about the recommendations made in the 2015 FDA Guidance.

117. Despite Defendants' admission that they were aware of the 2015 FDA Guidance, and that they intended to comply with it, the Company did not follow the 2015 FDA Guidance, and submitted only Category 1 (in vitro) studies to support labeling of Rexista for abuse deterrence related to *only* the IV route of abuse, when IPCI should have conducted a complete abuse-deterrent assessment to cover multiple routes of administration such as oral, intranasal, and IV abuse, and should have conducted Category 2 and 3 studies because they provide important information for the evaluation of abuse deterrent formulations with respect to oral and intranasal abuse that cannot be derived from Category 1 studies alone.

118. As a result, the FDA Advisory Committee overwhelmingly found that the IPCI's Rexista NDA should not be approved because IPCI did not follow the 2015 FDA Guidance: "***The panel believes, and I believe, that the guidelines need to be followed. I think the committee feels uncomfortable in providing a signal that it's all right to present incomplete data and expect a positive outcome***." Tr. 261:15-262:3 (emphasis added). The FDA Advisory Committee also released a report that stated that "[t]he safety information collected [by IPCI] in the pharmacokinetic studies was of limited value…. There were no human abuse liability studies submitted with the NDA."

B. IPCI's Executive Compensation Plans Provided Incentives for Defendants to Mislead Investors and Withhold Material Adverse Information

119. As reflected in IPCI's March 18, 2016 Proxy Statement, Defendant Odidi had performance-based options tied to "the Company attaining certain milestones relating to the United States Food and Drug Administration ("FDA") filings and approvals for the development of Company drugs, such that 276,394 options vest in connection with each of the FDA filings for the first five Company drugs and 276,394 options vest in connection with each of the FDA approvals for the first five Company drugs." Thus, Defendant Odidi was incentivized to make filings with the FDA for the Company's drugs to obtain lucrative performance-based options.

120. Moreover, the employment agreement with Defendant Odidi, the CEO of the Company, effective September 1, 2004 entitles Defendant Odidi to receive a base salary of U.S. $200,000 per year, which is paid in Canadian dollars, to be increased annually each year during the term of the agreement by twenty percent of the prior year's salary. In addition, he is entitled to: (a) participate in the Option Plan; (b) participate in all employee benefit plans and programs, except for the RSU Plan and DSU Plan; and (c) a car allowance of up to U.S. $1,000 per month.

121. In April 2010, Defendant Odidi offered and agreed to amend his employment agreement effective as of December 1, 2009, to eliminate the right to annual increases in his base salary of twenty per cent each year; and agreed to roll back his base salary effective December 1, 2009 to the level payable under the employment agreement for the period from September 2008 to August 2009, being C$452,000 per year.

122. In February 2012, Defendant Odidi received a grant of 300,000 options of which 200,000 vested immediately on issuance and the remaining 100,000 options vested on February 17, 2013 at an exercise price of $3.27 per share. In April 2013, Defendant Odidi received a grant of 75,000 options of which 37,500 vested immediately on issuance and the remaining 37,500

options vested on November 30, 2013 at an exercise price of $1.81 per share. In March 2014, Defendant Odidi received a grant of 50,000 options of which 25,000 vested immediately on issuance and the remaining 25,000 options vested on November 30, 2014 at an exercise price of $4.29 per share. In November 2015, Defendant Odidi received a grant of 70,000 options of which 49,000 vested immediately on issuance, with the remaining 21,000 options vested on November 30, 2016 at an exercise price of $2.52 per share. In August 2016, Defendant Odidi received a grant of 90,000 options of which 60,000 vested immediately on issuance, with the remaining 30,000 to vest on November 30, 2017 at an exercise price of $2.43 per share.

123. The employment agreement with Defendant Della Penna, the former CFO of the Company, effective November 24, 2014 entitles Defendant Della Penna to receive a base salary of C$275,000, which is paid in Canadian dollars, per year and which was increased by the Board on a discretionary basis for 2015 to C$300,000 and C$325,000 for 2017 and future years. In addition, he is entitled to: (a) participate in the Option Plan; (b) participate in all employee benefit plans and programs; and (c) a car allowance of C$1,500 per month.

124. Defendant Della Penna was granted 60,000 options, of which 15,000 vested immediately on issuance, 15,000 vested on November 30, 2015 and the remaining options vest as to 15,000 each year on November 30, 2016 and 2017 at an exercise price of $3.22 per share. In November 2015, Defendant Della Penna received a grant of 50,000 options of which 35,000 vested immediately on issuance, with the remaining 15,000 options vested on November 30, 2016 at an exercise price of $2.52 per share. In August 2016, Defendant Della Penna received a grant of 70,000 options, of which 47,000 vested immediately, with the remaining 23,000 to vest on November 30, 2017 at an exercise price of $2.43 per share.

C. The Company's Attempts to Secure a Partner for Rexista and IPCI's ATM Program Incentivized Defendants to Mislead the Public

125. Defendants were further motivated to issue false and misleading statements regarding the Company's potential for obtaining FDA approval of Rexista because the Company was purportedly attempting to secure a partner for Rexista to infuse much needed funds into the Company. *See* October 15, 2015 Form 6-K. For example, one analyst noted that "Management is evaluating partner options and sources of capital to fund this programs development." *See* May 21, 2015 Maxim Group report. Similarly, an analyst at Maxim Group stated, "As additional elements of the abuse technology are validated with 3rd part clinical studies we expect to see Rexista lead to a partnership opportunity that could trigger both capital and set the stage for the company to raise capital at a higher valuation…." *See* April 15, 2016 Maxim Group report. After the filing of the Rexista NDA, an analyst at Dawson James Securities noted that "we expect management will shift focus to discussions for a potential marketing partner for Rexista[.]" *See* February 3, 2017 Dawson James Securities report.

126. After it was revealed that the FDA Advisory Committee recommended that Rexista not be approved, one analyst noted that a partnership for Rexista could have brought in $7.5 million in licensing revenue, and that without such a partnership, the Company would likely need to raise funds down the road that would cause equity dilution:

> Looming Balance Sheet Risk: Based on our new estimates, IPCI could have a cash crunch. For now, until we have greater clarity, we are not assuming IPCI to forge a partnership for Rexista which we originally assumed to bring in $7.5M licensing revenues. IPCI is likely going to raise funds down the road that would cause equity dilution."

July 27, 2017 Mackie Research Capital Corporation report.

127. Another avenue that IPCI had to regularly rely on to raise funds was selling the Company's common shares under its ATM program. *See, e.g.,* Forms 6-K (and attached exhibits)

dated 7/13/15, 10/9/15, 2/26/16, 4/15/16, 7/13/16, 10/14/16, 2/10/17, 4/11/17, 7/11/17, and 10/10/17. Because shares in an ATM are sold at prevailing market prices, Defendants were also motivated to issue false and misleading statements regarding the Company's potential for obtaining FDA approval of Rexista in order to keep IPCI's stock at artificially inflated levels throughout the Class Period.

128. Notably, raising funds was critical because the Company had posted only net losses during the Class Period, and was constantly low on cash throughout that same time period:

Date	Quarter	Cash on Hand (in millions)	Net Loss for Quarter (in millions)
5/31/15	2Q:15	$3.0	($1.5)
8/31/15	3Q:15	$2.8	($1.9)
11/30/15	4Q:15	$1.8	($3.1)
2/25/16		$0.4	
2/29/16	1Q:16	$0.4	($2.1)
5/31/16	2Q:16	$0.2	($2.0)
7/12/16		$3.4	
8/31/16	3Q:16	$2.0	($2.1)
10/13/16		$4.5	
11/30/16	4Q:16	$4.1	($3.9)
2/9/17		$2.9	
2/28/17	1Q:17	$2.4	($2.0)
5/31/17	2Q:17	$1.5	($1.8)
7/11/17		$0.6	
8/31/17	3Q:17	$0.7	($2.6)
		TOTAL (approx.)	**($23.0)**

See Forms 6-K (and attached exhibits) dated 7/13/15, 10/9/15, 2/26/16, 4/15/16, 7/13/16, 10/14/16, 2/10/17, 4/11/17, 7/11/17, and 10/10/17.

129. Therefore, Defendants were motivated to issue materially false and misleading statements in order to improve their chances of securing a lucrative partnership for Rexista and so IPCI could raise cash at inflated levels to infuse much needed funds into the Company.

D. IPCI's June 2016 Public Offering Incentivized Defendants to Mislead the Public

130. Defendants were also motivated to issue false and misleading statements regarding the Company's potential for obtaining FDA approval of Rexista because in May 2016 the Company announced it intended to offer units of its common shares and warrants in an underwritten public offering in order to raise funds. *See* May 26, 2016 Form 6-K.

131. Ultimately, the Company announced that it received net proceeds of approximately $4.6 million, and that it intended to use these net proceeds "for working capital and for general corporate purposes, including funding research, product development and other corporate development opportunities." *See* June 6, 2016 Form 6-K. As of July 12, 2016, the Company had only "$3.4 million in cash, primarily due to its $4.6 million public offering in June." *See* July 14, 2016 Brean Capital, LLC report.

E. Suspiciously Timed Trading by Defendant Odidi Supports an Inference of Scienter

132. Defendant Odidi's suspiciously timed stock sale while in possession of material inside information about IPCI supports the inference that he acted with scienter in that he knew and/or recklessly disregarded facts available to him that demonstrated that the public documents and statements issued or disseminated by him individually or in the name of the Company were materially false and misleading.

133. Specifically, Defendant Odidi and his wife, Dr. Amina Odidi, the Company's President, COO, and co-CSO, through their privately-held company, "Odidi Holdings Inc.," sold 216,439 shares of IPCI at an average of $3.1814 per share on May 29, 2015 (for approximately $658,579.04)—just eight days after the start of the Class Period and three days after announcing the FDA granted IPCI's request for fast track designation. Notably, this sale equaled almost 44% of the stock's total trading volume (492,100) on May 29, 2015.

F. Other Suspicious Behavior by Defendant Odidi Supporting Motive and a Pattern and Practice of Concealing Material Information

134. On January 21, 2018, Atiku Abubakar, the former Vice President of Nigeria, announced (via Twitter) that Defendant Odidi became the first "Nigerian and African" to establish a new high tech pharmaceutical manufacturing and R&D company in China.[11] Mr. Abubakar also included photographs depicting Defendant Odidi at a signing ceremony for the event:

135. In response to that tweet, Defendant Odidi replied from what is believed to be his personal Twitter account, where he describes himself as the Chairman, CEO, and CSO at IPCI, that he was "grateful" that Mr. Abubakar publicly acknowledged his work in China:

[11] Several Nigerian news organizations also reported this story. *See, e.g.*, *Atiki hails Isa Odidi on overseas exploits, investments*, (Jan. 21, 2018), Newsdiaryonline, https://newsdiaryonline.com/atiku-hails-isa-odidi-overseas-exploits-investments/

136. The name of the new Chinese company is Smart Pharmaceutical (Shanghai) Co., Ltd. (which can be seen printed on the background in the photographs along with the names of IPCI and Shanghai Yunfeng Pharmaceutical). According to the Administration for Industry & Commerce of the People's Republic of China, Smart Pharmaceutical was founded/incorporated in May 2017—only two months before the FDA Advisory Committee meeting related to Rexista—and Defendant Odidi is listed as the chairman of the board of Smart Pharmaceutical. Moreover, the website of Shenyang Pharmaceutical University, where Defendant Odidi is purportedly a visiting professor, lists him as "Chairman, Founder and Chief Scientist" of Smart Pharmaceutical since May 2017.[12]

137. An article on the website of Shanghai Yunfeng Pharmaceutical reported that a "signing ceremony" related to a strategic partnership between Shanghai Yunfeng Pharmaceutical

[12] http://www.syphu.edu.cn/info/1004/4126.htm

and Smart Pharmaceutical took place on December 8, 2017.[13] The article further provides that the CEO of Smart Pharmaceutical, Yuan Aiping, and the general manager of Smart Pharmaceutical, Li Pengyu, attended the ceremony. The article also states that Li Pengyu attended the ceremony and ***signed the partnership agreement on behalf of the CEO of IPCI, Defendant Odidi***.

138. CW 7, who is currently employed at Yunfeng Pharmaceutical as a Quality Analyst and has been employed there since October 2012, corroborated this information. Specifically, CW 7 stated that Smart Pharmaceutical was introduced to them as a Canadian based pharmaceutical group, which is where IPCI is based, and that Defendant Odidi and Smart Pharmaceutical are currently involved in a partnership with Yunfeng Pharmaceutical, which was finalized in December 2017.

139. Per Yunfeng Pharmaceutical's website, Smart Pharmaceutical is an innovative pharmaceutical company recently founded in Shanghai by Defendant Odidi, and the new company will set up the largest R&D center for controlled-release drugs in Shanghai in China, which is remarkably similar to the description that IPCI provides of itself on its own website: "At Intellipharmaceutics, we are engaged in the research, development and commercialization of controlled-release and targeted pharmaceutical products…."[14]

140. Despite the obvious materiality of this information, neither IPCI nor Defendant Odidi disclosed that IPCI's founder and current CEO started a new, private Chinese company in the same industry as IPCI. Instead, on January 24, 2018, IPCI issued a materially misleading press release denying that the Company had entered into any arrangement in China: "[Although] [t]he Company recently visited China where discussions toward establishing a partnership to

[13] http://www.yunfeng-medicine.com/index.php/2017/12/16/cooperate/
[14] https://www.intellipharmaceutics.com/about

facilitate future development activities are ongoing[,] [t]he Company has not entered into any such arrangements at this time." *See* Ex. 99.1 to January 24, 2018 Form 6-K. The press release, however, conspicuously omits whether Defendant Odidi entered into any arrangements in China or whether he has a stake in Smart Pharmaceutical (Shanghai) Co., Ltd. or any other Chinese pharmaceutical companies.

141. Therefore, in addition to the appearance of impropriety, Defendant Odidi's undisclosed connection to this new, private Chinese pharmaceutical company, which appears to operate in the same space as IPCI, raises serious questions concerning, among other things, conflicts of interest with IPCI and possible breaches of duties owed to the Company's shareholders. This Chinese connection also calls into question Defendant Odidi's commitment to IPCI and Rexista.

G. Additional Allegations of Scienter

142. Defendants are also presumed to have detailed, inside knowledge about their principle product, Rexista. IPCI admitted that Rexista was a principal focus. For example, IPCI stated that it had "increased its research and development [] emphasis towards specialty new product development … by advancing the product development program for both Rexista and Regabatin." *See* Ex. 99.1 to Form 6-K filed February 29, 2016. Indeed, one analyst commented: "Although IPCI has eight additional ANDA filings pending approval, management has been guiding investor focus away from the ANDA pipeline towards increased focus on the Company's proprietary 505(b)2 candidates such as Rexista®." *See* February 27, 2017 Dawson James Securities report. Given the importance of Rexista to IPCI, Defendants knew or should have known that they overstated the possibility of success of NDA Rexista.

143. Additionally, as discussed above, several CWs reported that Defendant Odidi was a key person in any NDA submission, and he would have been central to the review and approval of any information included in every NDA. CW 2 stated that all NDA submissions would have to go through Defendant Odidi, and Defendant Odidi was a key person in any NDA submission. CW 3 stated that the NDA process for Rexista was the responsibility of Defendant Odidi and the company's other top executives. CW 4 stated that IPCI's senior leadership was "tight," that they controlled the NDA process, and that Defendant Odidi was a key person in all NDAs. Therefore, Defendant Odidi and other IPCI executives would have been intimately familiar with all aspects of the Rexista NDA. Finally, CW 6 corroborated that Defendant Odidi and Dr. Amina Odidi, in consultation with the Director of Regulatory Affairs, would have been involved in any internal discussions regarding what studies to do for any NDA.

144. Moreover, because of the Individual Defendants' positions with the Company, they each had access to the adverse undisclosed information about IPCI's business, operations, products, operational trends, financial statements, markets, and present and future business prospects via access to internal corporate documents (including the Company's operating plans, budgets and forecasts and reports of actual operations compared thereto), conversations and connections with other corporate officers and employees, attendance at management and Board of Directors meetings and committees thereof, and *via* reports and other information provided to them in connection therewith.

145. As officers and controlling persons of a publicly-held company whose securities are registered with the SEC pursuant to the Exchange Act, publicly traded, and governed by the provisions of the federal securities laws, Defendants Odidi and Della Penna each had a duty to promptly disseminate accurate and truthful information with respect to the Company's financial

condition and performance, growth, operations, financial statements, business, products, markets, management, earnings and present and future business prospects, and to correct any previously-issued statements that had become materially misleading or untrue, so that the market price of the Company's publicly-traded securities would be based upon truthful and accurate information. Odidi's and Della Penna's misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

146. Defendants Odidi and Della Penna participated in the drafting, preparation, and/or approval of the various public, shareholder, and investor reports and other communications complained of herein and were aware of, or recklessly disregarded, the misstatements contained therein and omissions there from, and were aware of their materially false and misleading nature. Because of their Board membership and/or executive and managerial positions with IPCI, Defendants Odidi and Della Penna each had access to the adverse undisclosed information about IPCI's business prospects and financial condition and performance as particularized herein and knew (or recklessly disregarded) that these adverse facts rendered the positive representations made by or about IPCI and its business issued or adopted by the Company materially false and misleading.

147. Defendants Odidi and Della Penna, because of their positions of control and authority as officers and/or directors of the Company, were able to and did control the content of the various SEC filings, press releases, and other public statements pertaining to the Company during the Class Period. Defendants Odidi and Della Penna each were provided with copies of the documents alleged herein to be misleading prior to or shortly after their issuance and/or had the ability and/or opportunity to prevent their issuance or cause them to be corrected. Accordingly, Defendants Odidi and Della Penna are each responsible for the accuracy of the

public reports and releases detailed herein and is therefore primarily liable for the representations contained therein.

148. Defendants Odidi and Della Penna are each liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of IPCI securities by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme**:** (a) deceived the investing public regarding IPCI's business, operations, management, and the intrinsic value of IPCI securities; (b) enabled Defendants to artificially inflate the price of IPCI shares; (c) caused Plaintiffs and other members of the Class to purchase IPCI securities at artificially inflated prices.

LOSS CAUSATION/ECONOMIC LOSS

149. During the Class Period, Defendants engaged in a scheme to deceive the market, and a course of conduct that artificially inflated IPCI's stock price and operated as a fraud on Class Period purchasers of IPCI's stock by making false and/or misleading statements about its NDA for Rexista. Ultimately, however, when Defendants' prior misrepresentations came to be revealed to investors, shares of IPCI declined precipitously—evidence that the prior artificial inflation in the price of IPCI's shares was eradicated—and, as a result of their purchases of IPCI stock during the Class Period at artificially inflated prices, Plaintiffs and other members of the Class suffered economic losses when the truth about the NDA for Rexista was finally and fully revealed and the artificial inflation was removed from price of the Company's stock, *i.e.*, damages under the federal securities laws.

150. Immediately upon the revelation of these previously undisclosed facts, IPCI stock plummeted over 45%, on moderate to heavy trading volume, from a closing price of $2.49 per share on July 26, 2017, to close at $1.36 per share at the end of trading on July 27, 2017.

151. The declines in the price of IPCI securities after the truth came to light were a direct result of the nature and extent of Defendants' fraud finally being revealed to investors and the market. The timing and magnitude of IPCI's stock price decline negates any inference that the loss suffered by Plaintiffs and the other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to Defendants' fraudulent conduct. The economic loss suffered by Plaintiffs and the other members of the Class was a direct result of Defendants' fraudulent scheme to artificially inflate the prices of IPCI's securities and the subsequent decline in the value of IPCI's securities when Defendants' prior misrepresentations, omissions, and other fraudulent conduct were revealed.

152. The economic loss, *i.e.*, damages suffered by Plaintiffs and other members of the Class, was a direct result of Defendants' misrepresentations and omissions being revealed to investors, and the subsequent significant decline in the value of the Company's shares was also the direct result of Defendants' prior misstatements and omissions being revealed.

APPLICABILITY OF PRESUMPTION OF RELIANCE:
FRAUD-ON-THE-MARKET DOCTRINE

153. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- The omissions and misrepresentations were material;
- IPCI's securities are traded in an efficient market;
- The Company's securities were liquid and traded with moderate to heavy volume during the Class Period;
- The Company traded on the NASDAQ, and was covered by multiple analysts;

- The misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and

- Plaintiffs and members of the Class purchased, acquired and/or sold IPCI securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

Based upon the foregoing, Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

STATUTORY SAFE HARBOR DOES NOT APPLY

154. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of the Company who knew that those statements were false when made.

CLASS ACTION ALLEGATIONS

155. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired IPCI securities during the Class Period (the "Class"); and were damaged

upon the revelation of the true facts. Excluded from the Class are Defendants herein, present and former officers and directors of the Company, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

156. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, IPCI's common stock was actively traded on NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by IPCI or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

157. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

158. Plaintiffs will fairly and adequately represent and protect the interests of the members of the Class and have retained counsel competent and experienced in class action and securities litigation.

159. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members. A class wide proceeding will generate common answers to the following questions of law and fact common to the Class, among others:

- Whether the federal securities laws were violated by Defendants' acts as alleged herein;

- Whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business and operations of IPCI, including the business prospects of IPCI and the prospects of approval for the Rexista NDA;

- Whether the Individual Defendants caused IPCI to issue materially false and misleading financial statements during the Class Period;

- Whether Defendants acted knowingly or recklessly in issuing false and misleading statements to investors;

- Whether the prices of IPCI's securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- Whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

160. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy, as joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action. Plaintiffs' allegations stem from Defendants' issuance of materially false and/or misleading statements and omissions during the Class Period contained in SEC filings, Company releases, and conference calls with analysts. These statements and omissions concealed true, adverse facts about, *inter alia*, Rexista and the likelihood of approval of the Rexista NDA.

CLAIMS FOR RELIEF

COUNT I

(For Violations of §10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

161. Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

162. Plaintiffs assert Section 10(b) and Rule 10b-5(a), (b) and (c) claims against all Defendants.

163. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC. Rule 10b-5(a) makes it unlawful for any person, directly or indirectly to employ any device, scheme, or artifice to defraud. Rule 10b-5(b) makes it unlawful for any person, directly or indirectly to make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading. Rule 10b-5(c) makes it unlawful for any person, directly or indirectly, to engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

164. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiffs and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of common stock. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of IPCI securities; and (iii) cause Plaintiffs and other members of the Class to purchase or otherwise

acquire IPCI securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

165. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for IPCI securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about IPCI's finances and business prospects.

166. As established by the facts alleged above, as well as by virtue of their positions at IPCI, Defendants had knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiffs and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Additional information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control.

167. IPCI is liable for all materially false and misleading statements and omissions made during the Class Period, as alleged above, including the false and misleading statements made by the Company's officers and agents, as alleged above, as the maker of such statements and under the principle of respondeat superior.

168. Defendants Odidi and Della Penna are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual

Defendants were able to and did, directly or indirectly, control the content of the statements of IPCI. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to IPCI's business, products, financial condition and prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of IPCI securities were artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning IPCI's business and financial condition which were concealed by Defendants, Plaintiffs and the other members of the Class purchased or otherwise acquired IPCI securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

169. During the Class Period, IPCI securities were traded on an active and efficient market. Plaintiffs and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired IPCI securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiffs and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiffs and the Class, the true value of IPCI securities were substantially lower than the prices paid by Plaintiffs and the other members of the Class. The market price of IPCI securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiffs and Class members.

170. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

171. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's common stock during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(For Violations of §20(a) of the Exchange Act against Defendants Odidi and Della Penna)

172. Plaintiffs repeat and re-allege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

173. Plaintiffs assert Section 20(a) claims against the Individual Defendants.

174. During the Class Period, the Individual Defendants directed the daily operation and management of IPCI, and directed the financial disclosures and statements to investors regarding, inter alia, IPCI's business operations.

175. As described above, the Individual Defendants knew the adverse non-public information about IPCI alleged herein.

176. As officers of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to IPCI's financial condition and prospects, and to correct promptly any public statements issued by IPCI, which had become materially false or misleading.

177. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which IPCI disseminated in the marketplace during the Class Period. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause IPCI to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of IPCI within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged that artificially inflated the market price of IPCI securities.

178. Each of the Individual Defendants therefore acted as a controlling person of IPCI, and by reason of the above conduct, is liable pursuant to Section 20(a) of the Exchange Act for the violations committed by IPCI. As a direct and proximate result of the Individual Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's stock during the Class Period and the related damages resulting after the true facts were revealed and the artificial inflation was removed from the price of the stock.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment as follows:

1. Determining that this action is a proper class action, certifying Plaintiffs as Class representatives under Rule 23 of the Federal Rules of Civil Procedure and Lead Counsel as Class Counsel;

2. Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

3. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees;

4. Awarding extraordinary, equitable and/or injunctive relief as permitted by law, equity and the federal statutory provisions sued hereunder; and

5. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

Dated: January 29, 2018

Respectfully submitted,

KAHN SWICK & FOTI, LLC

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was filed on January 29, 2018, and will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF), and paper copies will be sent to those indicated as non-registered participants on January 29, 2018.

/s/ *Kim E. Miller*
Kim E. Miller